

ORAL ARGUMENT NOT YET SCHEDULED

No. 25-1005

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

CENTER FOR BIOLOGICAL DIVERSITY,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

LEE ZELDIN, Administrator

Respondents,

*Petition for Review of Final Administrative Action of the
United States Environmental Protection Agency*

**ADDENDUM OF STATUTES AND REGULATIONS
IN SUPPORT OF PETITIONERS' OPENING BRIEF
VOLUME 1 OF 3**

RYAN MAHER
Center for Biological Diversity
1411 K Street, NW, Suite 1300
Washington, DC 20005
Tel: (781) 325-6303
Email: rmaher@biologicaldiversity.org
Counsel for Petitioner

JONATHAN EVANS
Center for Biological Diversity
2100 Franklin St., Suite 375
Oakland, CA 94612
Tel: (213) 598-1466
Email: jevans@biologicaldiversity.org
Counsel for Petitioner

ADDENDUM OF STATUTES AND REGULATIONS

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5 USCS § 706

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

- (1)** compel agency action unlawfully withheld or unreasonably delayed; and
- (2)** hold unlawful and set aside agency action, findings, and conclusions found to be—

- (A)** arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

- (B)** contrary to constitutional right, power, privilege, or immunity;

- (C)** in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

- (D)** without observance of procedure required by law;

- (E)** unsupported by substantial evidence in a case subject to sections 556 and 557 of this title [5 USCS §§ 556 and 557] or otherwise reviewed on the record of an agency hearing provided by statute; or

- (F)** unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

16 USCS § 1536

§1536. Interagency cooperation

(a) Federal agency actions and consultations.

(1) The Secretary shall review other programs administered by him and utilize such programs in furtherance of the purposes of this Act. All other Federal agencies shall, in consultation with and with the assistance of the Secretary, utilize their authorities in furtherance of the purposes of this Act by carrying out programs for the conservation of endangered species and threatened species listed pursuant to section 4 of this Act [16 USCS § 1533].

(2) Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency (hereinafter in this section referred to as an “agency action”) is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of habitat of such species which is determined by the Secretary, after consultation as appropriate with affected States, to be critical, unless such agency has been granted an exemption for such action by the Committee pursuant to subsection (h) of this section. In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available.

(3) Subject to such guidelines as the Secretary may establish, a Federal agency shall consult with the Secretary on any prospective agency action at

the request of, and in cooperation with, the prospective permit or license applicant if the applicant has reason to believe that an endangered species or a threatened species may be present in the area affected by his project and that implementation of such action will likely affect such species.

(4) Each Federal agency shall confer with the Secretary on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under section 4 [16 USCS § 1533] or result in the destruction or adverse modification of critical habitat proposed to be designated for such species. This paragraph does not require a limitation on the commitment of resources as described in subsection (d).

(b) Opinion of Secretary.

(1)

(A) Consultation under subsection (a)(2) with respect to any agency action shall be concluded within the 90-day period beginning on the date on which initiated or, subject to subparagraph (B), within such other period of time as is mutually agreeable to the Secretary and the Federal agency.

(B) In the case of an agency action involving a permit or license applicant, the Secretary and the Federal agency may not mutually agree to conclude consultation within a period exceeding 90 days

unless the Secretary, before the close of the 90th day referred to in subparagraph (A)—

(i) if the consultation period proposed to be agreed to will end before the 150th day after the date on which consultation was initiated, submits to the applicant a written statement setting forth—

(I) the reasons why a longer period is required,

(II) the information that is required to complete the consultation, and

(III) the estimated date on which consultation will be completed; or

(ii) if the consultation period proposed to be agreed to will end 150 or more days after the date on which consultation was initiated, obtains the consent of the applicant to such period.

The Secretary and the Federal agency may mutually agree to extend a consultation period established under the preceding sentence if the Secretary, before the close of such period, obtains the consent of the applicant to the extension.

(2) Consultation under subsection (a)(3) shall be concluded within such period as is agreeable to the Secretary, the Federal agency, and the applicant concerned.

(3)

(A) Promptly after conclusion of consultation under paragraph (2) or (3) of subsection (a), the Secretary shall provide to the Federal agency and the applicant, if any, a written statement setting forth the Secretary's opinion, and a summary of the information on which the opinion is based, detailing how the agency action affects the species or its critical habitat. If jeopardy or adverse modification is found, the Secretary shall suggest those reasonable and prudent alternatives which he believes would not violate subsection (a)(2) and can be taken by the Federal agency or applicant in implementing the agency action.

(B) Consultation under subsection (a)(3), and an opinion issued by the Secretary incident to such consultation, regarding an agency action shall be treated respectively as a consultation under subsection (a)(2), and as an opinion issued after consultation under such subsection, regarding that action if the Secretary reviews the action before it is commenced by the Federal agency and finds, and notifies such agency, that no significant changes have been made with respect to the action and that no significant change has occurred regarding the information used during the initial consultation.

(4) If after consultation under subsection (a)(2), the Secretary concludes that—

(A) the agency action will not violate such subsection, or offers reasonable and prudent alternatives which the Secretary believes would not violate such subsection;

(B) the taking of an endangered species or a threatened species incidental to the agency action will not violate such subsection; and

(C) if an endangered species or threatened species of a marine mammal is involved, the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972 [16 USCS §§ 1361 et seq.]

the Secretary shall provide the Federal agency and the applicant concerned, if any, with a written statement that—

(i) specifies the impact of such incidental taking on the species,

(ii) specifies those reasonable and prudent measures that the Secretary considers necessary or appropriate to minimize such impact,

(iii) in the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 [16 USCS §§ 1361 et seq.] with regard to such taking, and

(iv) sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or applicant (if any), or both, to implement the measures specified under clauses (ii) and (iii).

42 USCS § 7407

§ 7407. Air quality control regions

(a) Responsibility of each State for air quality; submission of implementation plan. Each State shall have the primary responsibility for assuring air quality within the entire geographic area comprising such State by submitting an implementation plan for such State which will specify the manner in which national primary and secondary ambient air quality standards will be achieved and maintained within each air quality control region in such State.

(b) Designated regions. For purposes of developing and carrying out implementation plans under section 110 [42 USCS § 7410]—

(1) an air quality control region designated under this section before the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], or a region designated after such date under subsection (c), shall be an air quality control region; and

(2) the portion of such State which is not part of any such designated region shall be an air quality control region, but such portion may be subdivided by the State into two or more air quality control regions with the approval of the Administrator.

(c) Authority of Administrator to designate regions; notification of Governors of affected States. The Administrator shall, within 90 days after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], after

consultation with appropriate State and local authorities, designate as an air quality control region any interstate area or major intrastate area which he deems necessary or appropriate for the attainment and maintenance of ambient air quality standards. The Administrator shall immediately notify the Governors of the affected States of any designation made under this subsection.

(d) Designations.

(1) Designations generally.

(A) Submission by Governors of initial designations following promulgation of new or revised standards. By such date as the Administrator may reasonably require, but not later than 1 year after promulgation of a new or revised national ambient air quality standard for any pollutant under section 109 [42 USCS § 7409], the Governor of each State shall (and at any other time the Governor of a State deems appropriate the Governor may) submit to the Administrator a list of all areas (or portions thereof) in the State, designating as—

(i) nonattainment, any area that does not meet (or that contributes to ambient air quality in a nearby area that does not meet) the national primary or secondary ambient air quality standard for the pollutant,

(ii) attainment, any area (other than an area identified in clause (i)) that meets the national primary or secondary ambient air quality standard for the pollutant, or

(iii) unclassifiable, any area that cannot be classified on the basis of available information as meeting or not meeting the national primary or secondary ambient air quality standard for the pollutant.

The Administrator may not require the Governor to submit the required list sooner than 120 days after promulgating a new or revised national ambient air quality standard.

(B) Promulgation by EPA of designations.

(i) Upon promulgation or revision of a national ambient air quality standard, the Administrator shall promulgate the designations of all areas (or portions thereof) submitted under subparagraph (A) as expeditiously as practicable, but in no case later than 2 years from the date of promulgation of the new or revised national ambient air quality standard. Such period may be extended for up to one year in the event the Administrator has insufficient information to promulgate the designations.

(ii) In making the promulgations required under clause (i), the Administrator may make such modifications as the

Administrator deems necessary to the designations of the areas (or portions thereof) submitted under subparagraph (A) (including to the boundaries of such areas or portions thereof). Whenever the Administrator shall notify the State and provide such State with an opportunity to demonstrate why any proposed modification is inappropriate. The Administrator shall give such notification no later than 120 days before the date the Administrator promulgates the designation, including any modification thereto. If the Governor fails to submit the list in whole or in part, as required under subparagraph (A), the Administrator shall promulgate the designation that the Administrator deems appropriate for any area (or portion thereof) not designated by the State.

(iii) If the Governor of any State, on the Governor's own motion, under subparagraph (A), submits a list of areas (or portions thereof) in the State designated as nonattainment, attainment, or unclassifiable, the Administrator shall act on such designations in accordance with the procedures under paragraph (3) (relating to redesignation).

(iv) A designation for an area (or portion thereof) made pursuant to this subsection shall remain in effect until the area

(or portion thereof) is redesignated pursuant to paragraph (3) or (4).

(C) Designations by operation of law.

(i) Any area designated with respect to any air pollutant under the provisions of paragraph (1) (A), (B), or (C) of this subsection (as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) is designated, by operation of law, as a nonattainment area for such pollutant within the meaning of subparagraph (A)(i).

(ii) Any area designated with respect to any air pollutant under the provisions of paragraph (1)(E) (as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) is designated by operation of law, as an attainment area for such pollutant within the meaning of subparagraph (A)(ii).

(iii) Any area designated with respect to any air pollutant under the provisions of paragraph (1)(D) (as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) is designated, by operation of law, as an unclassifiable area for such pollutant within the meaning of subparagraph (A)(iii).

(2) Publication of designations and redesignations.

(A) The Administrator shall publish a notice in the Federal Register promulgating any designation under paragraph (1) or (5), or announcing any designation under paragraph (4), or promulgating any redesignation under paragraph (3).

(B) Promulgation or announcement of a designation under paragraph (1), (4) or (5) shall not be subject to the provisions of sections 553 through 557 of title 5 of the United States Code (relating to notice and comment), except nothing herein shall be construed as precluding such public notice and comment whenever possible.

(3) Redesignation.

(A) Subject to the requirements of subparagraph (E), and on the basis of air quality data, planning and control considerations, or any other air quality-related considerations the Administrator deems appropriate, the Administrator may at any time notify the Governor of any State that available information indicates that the designation of any area or portion of an area within the State or interstate area should be revised. In issuing such notification, which shall be public, to the Governor, the Administrator shall provide such information as the Administrator may have available explaining the basis for the notice.

(B) No later than 120 days after receiving a notification under subparagraph (A), the Governor shall submit to the Administrator such redesignation, if any, of the appropriate area (or areas) or portion thereof within the State or interstate area, as the Governor considers appropriate.

(C) No later than 120 days after the date described in subparagraph (B) (or paragraph (1)(B)(iii)), the Administrator shall promulgate the redesignation, if any, of the area or portion thereof, submitted by the Governor in accordance with subparagraph (B), making such modifications as the Administrator may deem necessary, in the same manner and under the same procedure as is applicable under clause (ii) of paragraph (1)(B), except that the phrase “60 days” shall be substituted for the phrase “120 days” in that clause. If the Governor does not submit, in accordance with subparagraph (B), a redesignation for an area (or portion thereof) identified by the Administrator under subparagraph (A), the Administrator shall promulgate such redesignation, if any, that the Administrator deems appropriate.

(D) The Governor of any State may, on the Governor’s own motion, submit to the Administrator a revised designation of any area or portion thereof within the State. Within 18 months of receipt of a complete State redesignation submittal, the Administrator shall approve or deny such redesignation. The submission of a redesignation by a Governor shall not affect the effectiveness or enforceability of the applicable implementation plan for the State.

(E) The Administrator may not promulgate a redesignation of a nonattainment area (or portion thereof) to attainment unless—

(i) the Administrator determines that the area has attained the national ambient air quality standard;

(ii) the Administrator has fully approved the applicable implementation plan for the area under section 110(k) [42 USCS § 7410(k)];

(iii) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable implementation plan and applicable Federal air pollutant control regulations and other permanent and enforceable reductions;

(iv) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A [42 USCS § 7505a]; and

(v) the State containing such area has met all requirements applicable to the area under section 110 and part D [42 USCS § 7410 and §§ 7501 et seq.].

(F) The Administrator shall not promulgate any redesignation of any area (or portion thereof) from nonattainment to unclassifiable.

(4) Nonattainment designations for ozone, carbon monoxide and particulate matter (PM-10).

(A) Ozone and carbon monoxide.

(i) Within 120 days after the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], each Governor of each State shall submit to the Administrator a list that designates, affirms or reaffirms the designation of, or redesignates (as the case may be), all areas (or portions thereof) of the Governor's State as attainment, nonattainment, or unclassifiable with respect to the national ambient air quality standards for ozone and carbon monoxide.

(ii) No later than 120 days after the date the Governor is required to submit the list of areas (or portions thereof) required under clause (i) of this subparagraph, the Administrator shall promulgate such designations, making such modifications as the Administrator may deem necessary, in the same manner, and under the same procedure, as is applicable under clause (ii) of paragraph (1)(B), except that the phrase "60 days" shall be substituted for the phrase "120 days" in that clause. If the Governor does not submit, in accordance with clause (i) of this subparagraph, a designation for an area (or portion thereof), the Administrator shall promulgate the designation that the Administrator deems appropriate.

(iii) No nonattainment area may be redesignated as an attainment area under this subparagraph.

(iv) Notwithstanding paragraph (1)(C)(ii) of this subsection, if an ozone or carbon monoxide nonattainment area located within a metropolitan statistical area or consolidated metropolitan statistical area (as established by the Bureau of the Census) is classified under part D of this title [42 USCS §§ 7501 et seq.] as a Serious, Severe, or Extreme Area, the boundaries of such area are hereby revised (on the date 45 days after such classification) by operation of law to include the entire metropolitan statistical area or consolidated metropolitan statistical area, as the case may be, unless within such 45-day period the Governor (in consultation with State and local air pollution control agencies) notifies the Administrator that additional time is necessary to evaluate the application of clause (v). Whenever a Governor has submitted such a notice to the Administrator, such boundary revision shall occur on the later of the date 8 months after such classification or 14 months after the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990] unless the Governor makes the finding referred to in clause (v), and the Administrator concurs in such finding, within such period. Except as otherwise provided in this paragraph, a boundary revision under this clause or clause (v) shall apply for purposes of any State implementation plan

revision required to be submitted after the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990].

(v) Whenever the Governor of a State has submitted a notice under clause (iv), the Governor, in consultation with State and local air pollution control agencies, shall undertake a study to evaluate whether the entire metropolitan statistical area or consolidated metropolitan statistical area should be included within the nonattainment area.

Whenever a Governor finds and demonstrates to the satisfaction of the Administrator, and the Administrator concurs in such finding, that with respect to a portion of a metropolitan statistical area or consolidated metropolitan statistical area, sources in the portion do not contribute significantly to violation of the national ambient air quality standard, the Administrator shall approve the Governor's request to exclude such portion from the nonattainment area. In making such finding, the Governor and the Administrator shall consider factors such as population density, traffic congestion, commercial development, industrial development, meteorological conditions, and pollution transport.

(B) PM-10 designations. By operation of law, until redesignation by the Administrator pursuant to paragraph (3)—

(i) each area identified in 52 Federal Register 29383 (Aug. 7, 1987) as a Group I area (except to the extent that such identification was

modified by the Administrator before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) is designated nonattainment for PM-10;

(ii) any area containing a site for which air quality monitoring data show a violation of the national ambient air quality standard for PM-10 before January 1, 1989 (as determined under part 50, appendix K of title 40 of the Code of Federal Regulations) is hereby designated nonattainment for PM-10; and

(iii) each area not described in clause (i) or (ii) is hereby designated unclassifiable for PM-10.

Any designation for particulate matter (measured in terms of total suspended particulates) that the Administrator promulgated pursuant to this subsection (as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) shall remain in effect for purposes of implementing the maximum allowable increases in concentrations of particulate matter (measured in terms of total suspended particulates) pursuant to section 163(b) [42 USCS § 7473(b)], until the Administrator determines that such designation is no longer necessary for that purpose.

(5) Designations for lead. The Administrator may, in the Administrator's discretion at any time the Administrator deems appropriate, require a State to designate areas (or portions thereof) with respect to the national ambient air quality standard for

lead in effect as of the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], in accordance with the procedures under subparagraphs (A) and (B) of paragraph (1), except that in applying subparagraph (B)(i) of paragraph (1) the phrase “2 years from the date of promulgation of the new or revised national ambient air quality standard” shall be replaced by the phrase “1 year from the date the Administrator notifies the State of the requirement to designate areas with respect to the standard for lead”.

(6) Designations.

(A) Submission. Notwithstanding any other provision of law, not later than February 15, 2004, the Governor of each State shall submit designations referred to in paragraph (1) for the July 1997 PM_{2.5} national ambient air quality standards for each area within the State, based on air quality monitoring data collected in accordance with any applicable Federal reference methods for the relevant areas.

(B) Promulgation. Notwithstanding any other provision of law, not later than December 31, 2004, the Administrator shall, consistent with paragraph (1), promulgate the designations referred to in subparagraph (A) for each area of each State for the July 1997 PM_{2.5} national ambient air quality standards.

(7) Implementation plan for regional haze.

(A) In general. Notwithstanding any other provision of law, not later than 3 years after the date on which the Administrator promulgates the designations

referred to in paragraph (6)(B) for a State, the State shall submit, for the entire State, the State implementation plan revisions to meet the requirements promulgated by the Administrator under section 169B(e)(1) [42 USCS § 7492(e)(1)] (referred to in this paragraph as “regional haze requirements”).

(B) No preclusion of other provisions. Nothing in this paragraph precludes the implementation of the agreements and recommendations stemming from the Grand Canyon Visibility Transport Commission Report dated June 1996, including the submission of State implementation plan revisions by the States of Arizona, California, Colorado, Idaho, Nevada, New Mexico, Oregon, Utah, or Wyoming by December 31, 2003, for implementation of regional haze requirements applicable to those States.”.

(e) Redesignation of air quality control regions.

(1) Except as otherwise provided in paragraph (2), the Governor of each State is authorized, with the approval of the Administrator, to redesignate from time to time the air quality control regions within such State for purposes of efficient and effective air quality management. Upon such redesignation, the list under subsection (d) shall be modified accordingly.

(2) In the case of an air quality control region in a State, or part of such region, which the Administrator finds may significantly affect air pollution concentrations in another State, the Governor of the State in which such region, or part of a region, is located may redesignate from time to time the

boundaries of so much of such air quality control region as is located within such State only with the approval of the Administrator and with the consent of all Governors of all States which the Administrator determines may be significantly affected.

(3) No compliance date extension granted under section 113(d)(5) (relating to coal conversion) shall cease to be effective by reason of the regional limitation provided in section 113(d)(5) if the violation of such limitation is due solely to a redesignation of a region under this subsection.

42 USCS 7408**§ 7408. Air quality criteria and control techniques****(a) Air pollutant list; publication and revision by Administrator; issuance of air quality criteria for air pollutants.**

(1) For the purpose of establishing national primary and secondary ambient air quality standards, the Administrator shall within 30 days after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970] publish, and shall from time to time thereafter revise, a list which includes each air pollutant—

(A) emissions of which, in his judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;

(B) the presence of which in the ambient air results from numerous or diverse mobile or stationary sources; and

(C) for which air quality criteria had not been issued before the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], but for which he plans to issue air quality criteria under this section.

(2) The Administrator shall issue air quality criteria for an air pollutant within 12 months after he has included such pollutant in a list under paragraph (1). Air quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all

identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities. The criteria for an air pollutant, to the extent practicable, shall include information on—

(A) those variable factors (including atmospheric conditions) which of themselves or in combination with other factors may alter the effects on public health or welfare of such air pollutant:

(B) the types of air pollutants which, when present in the atmosphere, may interact with such pollutant to produce an adverse effect on public health or welfare; and

(C) any known or anticipated adverse effects on welfare.

(b) Issuance by Administrator of information on air pollution control techniques; standing consulting committees for air pollutants; establishment; membership.

(1) Simultaneously with the issuance of criteria under subsection (a), the Administrator shall, after consultation with appropriate advisory committees and Federal departments and agencies, issue to the States and appropriate air pollution control agencies information on air pollution control techniques, which information shall include data relating to the cost of installation and operation, energy requirements, emission reduction benefits, and environmental impact of the emission control technology. Such information shall include such data as are available on available technology and

alternative methods of prevention and control of air pollution. Such information shall also include data on alternative fuels, processes, and operating methods which will result in elimination or significant reduction of emissions.

(2) In order to assist in the development of information on pollution control techniques, the Administrator may establish a standing consulting committee for each air pollutant included in a list published pursuant to subsection (a)(1), which shall be comprised of technically qualified individuals representative of State and local governments, industry, and the academic community. Each such committee shall submit, as appropriate, to the Administrator information related to that required by paragraph (1).

(c) Review, modification, and reissuance of criteria or information. The Administrator shall from time to time review, and, as appropriate, modify, and reissue any criteria or information on control techniques issued pursuant to this section. Not later than six months after the date of the enactment of the Clean Air Act Amendments of 1977 [enacted Aug. 7, 1977], the Administrator shall revise and reissue criteria relating to concentrations of NO₂ over such period (not more than three hours) as he deems appropriate. Such criteria shall include a discussion of nitric and nitrous acids, nitrites, nitrates, nitrosamines, and other carcinogenic and potentially carcinogenic derivatives of oxides of nitrogen.

(d) Publication in Federal Register; availability of copies for general public. The issuance of air quality criteria and information on air pollution control techniques shall be announced in the Federal Register and copies shall be made available to the general public.

(e) Transportation planning and guidelines. The Administrator shall, after consultation with the Secretary of Transportation, and after providing public notice and opportunity for comment, and with State and local officials, within nine months after enactment of the Clean Air Act Amendments of 1989 and periodically thereafter as necessary to maintain a continuous transportation-air quality planning process, update the June 1978 Transportation-Air Quality Planning Guidelines and publish guidance on the development and implementation of transportation and other measures necessary to demonstrate and maintain attainment of national ambient air quality standards. Such guidelines shall include information on—

- (1)** methods to identify and evaluate alternative planning and control activities;
- (2)** methods of reviewing plans on a regular basis as conditions change or new information is presented;
- (3)** identification of funds and other resources necessary to implement the plan, including interagency agreements on providing such funds and resources;

(4) methods to assure participation by the public in all phases of the planning process; and

(5) such other methods as the Administrator determines necessary to carry out a continuous planning process.

(f) Information regarding processes, procedures, and methods to reduce or control pollutants in transportation; reduction of mobile source related pollutants; reduction of impact on public health.

(1) The Administrator shall publish and make available to appropriate Federal, State, and local environmental and transportation agencies not later than one year after enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], and from time to time thereafter—

(A) information prepared, as appropriate, in consultation with the Secretary of Transportation, and after providing public notice and opportunity for comment, regarding the formulation and emission reduction potential of transportation control measures related to criteria pollutants and their precursors, including, but not limited to—

(i) programs for improved public transit;

(ii) restriction of certain roads or lanes to, or construction of such roads or lanes for use by, passenger buses or high occupancy vehicles;

(iii) employer-based transportation management plans, including incentives;

(iv) trip-reduction ordinances;

(v) traffic flow improvement programs that achieve emission reductions;

(vi) fringe and transportation corridor parking facilities serving multiple occupancy vehicle programs or transit service;

(vii) programs to limit or restrict vehicle use in downtown areas or other areas of emission concentration particularly during periods of peak use;

(viii) programs for the provision of all forms of high-occupancy, shared-ride services;

(ix) programs to limit portions of road surfaces or certain sections of the metropolitan area to the use of non-motorized vehicles or pedestrian use, both as to time and place;

(x) programs for secure bicycle storage facilities and other facilities, including bicycle lanes, for the convenience and protection of bicyclists, in both public and private areas;

(xi) programs to control extended idling of vehicles;

(xii) programs to reduce motor vehicle emissions, consistent with title II [42 USCS §§ 7521 et seq.], which are caused by extreme cold start conditions;

(xiii) employer-sponsored programs to permit flexible work schedules;

(xiv) programs and ordinances to facilitate non-automobile travel, provision and utilization of mass transit, and to generally reduce the need for single-occupant vehicle travel, as part of transportation planning and development efforts of a locality, including programs and ordinances applicable to new shopping centers, special events, and other centers of vehicle activity;

(xv) programs for new construction and major reconstructions of paths, tracks or areas solely for the use by pedestrian or other non-motorized means of transportation when economically feasible and in the public interest. For purposes of this clause, the Administrator shall also consult with the Secretary of the Interior; and

(xvi) program to encourage the voluntary removal from use and the marketplace of pre-1980 model year light duty vehicles and pre-1980 model light duty trucks.[;]

(B) information on additional methods or strategies that will contribute to the reduction of mobile source related pollutants during periods in which any primary ambient air quality standard will be exceeded and during episodes for which an air pollution alert, warning, or emergency has been declared;

(C) information on other measures which may be employed to reduce the impact on public health or protect the health of sensitive or susceptible individuals or groups; and

(D) information on the extent to which any process, procedure, or method to reduce or control such air pollutant may cause an increase in the emissions or formation of any other pollutant.

(2) In publishing such information the Administrator shall also include an assessment of—

(A) the relative effectiveness of such processes, procedures, and methods;

(B) the potential effect of such processes, procedures, and methods on transportation systems and the provision of transportation services; and

(C) the environmental, energy, and economic impact of such processes, procedures, and methods.

(g) Assessment of risks to ecosystems. The Administrator may assess the risks to ecosystems from exposure to criteria air pollutants (as identified by the Administrator in the Administrator's sole discretion).

(h) RACT/BACT/LAER clearinghouse. The Administrator shall make information regarding emission control technology available to the States and to the general public through a central database. Such information shall include all control technology information received pursuant to State plan provisions requiring permits for sources, including operating permits for existing sources.

42 USCS § 7409**§ 7409. National primary and secondary ambient air quality standards****(a) Promulgation.****(1) The Administrator—**

(A) within 30 days after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], shall publish proposed regulations prescribing a national primary ambient air quality standard and a national secondary ambient air quality standard for each air pollutant for which air quality criteria have been issued prior to such date of enactment; and

(B) after a reasonable time for interested persons to submit written comments thereon (but no later than 90 days after the initial publication of such proposed standards) shall be regulation promulgate such proposed national primary and secondary ambient air quality standards with such modifications as he deems appropriate.

(2) With respect to any air pollutant for which air quality criteria are issued after the date of enactment of the Clean Air Amendments of 1970 [enacted Dec. 31, 1970], the Administrator shall publish, simultaneously with the issuance of such criteria and information, proposed national primary and secondary ambient air quality standards for any such pollutant. The

procedure provided for in paragraph (1)(B) of this subsection shall apply to the promulgation of such standards.

(b) Protection of public health and welfare.

(1) National primary ambient air quality standards, prescribed under subsection (a) shall be ambient air quality standards the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health. Such primary standards may be revised in the same manner as promulgated.

(2) Any national secondary ambient air quality standard prescribed under subsection (a) shall specify a level of air quality the attainment and maintenance of which in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant in the ambient air. Such secondary standards may be revised in the same manner as promulgated.

(c) National primary ambient air quality standard for nitrogen dioxide. The Administrator shall, not later than one year after the date of the enactment of the Clean Air Act Amendments of 1977 [enacted Aug. 7, 1977], promulgate a national primary ambient air quality standard for NO₂ concentrations over a period of not more than 3 hours unless, based on the criteria issued under section 108(c) [42

USCS § 7408(c)], he finds that there is no significant evidence that such a standard for such a period is requisite to protect public health.

(d) Review and revision of criteria and standards; independent scientific review committee; appointment; advisory functions.

(1) Not later than December 31, 1980, and at five-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 [42 USCS § 7408] and the national ambient air quality standards promulgated under this section and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate in accordance with section 108 [42 USCS § 7408] and subsection (b) of this section. The Administrator may review and revise criteria or promulgate new standards earlier or more frequently than required under this paragraph.

(2)

(A) The Administrator shall appoint an independent scientific review committee composed of seven members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies.

(B) Not later than January 1, 1980, and at five-year intervals thereafter, the committee referred to in subparagraph (A) shall complete a review of the criteria published under section 108 [42 USCS § 7408] and the national primary and secondary ambient air quality standards promulgated under this section and shall recommend to the Administrator any new national ambient

air quality standards and revisions of existing criteria and standards as may be appropriate under section 108 [42 USCS § 7408] and subsection (b) of this section.

(C) Such committee shall also (i) advise the Administrator of areas in which additional knowledge is required to appraise the adequacy and basis of existing, new, or revised national ambient air quality standards, (ii) describe the research efforts necessary to provide the required information, (iii) advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and (iv) advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

42 USCS § 7410**§ 7410. State implementation plans for national primary and secondary ambient air quality standards****(a) Adoption of plan by State; submission to Administrator; content of plan; revision; new sources; indirect source review program; supplemental or intermittent control systems.**

(1) Each State shall, after reasonable notice and public hearings, adopt and submit to the Administrator, within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof) under section 109 [42 USCS § 7409] for any air pollutant, a plan which provides for implementation, maintenance, and enforcement of such primary standard in each air quality control region (or portion thereof) within such State. In addition, such State shall adopt and submit to the Administrator (either as a part of a plan submitted under the preceding sentence or separately) within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national ambient air quality secondary standard (or revision thereof), a plan which provides for implementation, maintenance, and enforcement of such secondary standard in each air quality control region (or portion thereof) within such State. Unless a separate public hearing is provided, each State shall consider its plan implementing such secondary standard at the hearing required by the first sentence of this paragraph.

(2) Each implementation plan submitted by a State under this Act shall be adopted by the State after reasonable notice and public hearing. Each such plan shall—

(A) include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements of this Act;

(B) provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to—

(i) monitor, compile, and analyze data on ambient air quality, and

(ii) upon request, make such data available to the Administrator;

(C) include a program to provide for the enforcement of the measures described in subparagraph (A), and regulation of the modification and construction of any stationary source within the areas covered by the plan as necessary to assure that national ambient air quality standards are achieved, including a permit program as required in parts C and D [42 USCS §§ 7470 et seq., 7501 et seq.];

(D) contain adequate provisions—

(i) prohibiting, consistent with the provisions of this title, any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will—

(I) contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any such national primary or secondary ambient air quality standard, or

(II) interfere with measures required to be included in the applicable implementation plan for any other State under part C [42 USCS §§ 7470 et seq.] to prevent significant deterioration of air quality or to protect visibility,

(ii) insuring compliance with the applicable requirements of sections 126 and 115 [42 USCS §§ 7426, 7415] (relating to interstate and international pollution abatement);

(E) provide (i) necessary assurances that the State (or, except where the Administrator deems inappropriate, the general purpose local government or governments, or a regional agency designated by the State or general purpose local governments for such purpose) will have adequate personnel, funding, and authority under State (and, as appropriate, local) law to carry out such implementation plan (and is not prohibited by any provision of Federal or State law from carrying out such implementation plan or portion thereof), (ii) requirements that the State comply with the requirements respecting State boards

under section 128 [42 USCS § 7428], and (iii) necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any plan provision, the State has responsibility for ensuring adequate implementation of such plan provision;

(F) require, as may be prescribed by the Administrator—

(i) the installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources,

(ii) periodic reports on the nature and amounts of emissions and emissions-related data from such sources, and

(iii) correlation of such reports by the State agency with any emission limitations or standards established pursuant to this Act, which reports shall be available at reasonable times for public inspection;

(G) provide for authority comparable to that in section 303 [42 USCS § 7603] and adequate contingency plans to implement such authority;

(H) provide for revision of such plan—

(i) from time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality

standard or the availability of improved or more expeditious methods of attaining such standard, and

(ii) except as provided in paragraph (3)(C), whenever the Administrator finds on the basis of information available to the Administrator that the plan is substantially inadequate to attain the national ambient air quality standard which it implements or to otherwise comply with any additional requirements established under this Act;

(I) in the case of a plan or plan revision for an area designated as a nonattainment area, meet the applicable requirements of part D [42 USCS §§ 7501 et seq.] (relating to nonattainment areas);

(J) meet the applicable requirements of section 121 [42 USCS § 7421] (relating to consultation), section 127 [42 USCS § 7427] (relating to public notification), and part C [42 USCS §§ 7470 et seq.] (relating to prevention of significant deterioration of air quality and visibility protection);

(K) provide for—

(i) the performance of such air quality modeling as the Administrator may prescribe for the purpose of predicting the effect on ambient air quality of any emissions of any air pollutant for which the Administrator has established a national ambient air quality standard, and

(ii) the submission, upon request, of data related to such air quality modeling to the Administrator;

(L) require the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under this Act, a fee sufficient to cover—

(i) the reasonable costs of reviewing and acting upon any application for such a permit, and

(ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action),

until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V [42 USCS §§ 7661 et seq.]; and

(M) provide for consultation and participation by local political subdivisions affected by the plan.

(3)

(A) [Repealed]

(B) As soon as practicable, the Administrator shall, consistent with the purposes of this Act and the Energy Supply and Environmental Coordination Act of 1974, review each State's applicable

implementation plans and report to the State on whether such plans can be revised in relation to fuel burning stationary sources (or persons supplying fuel to such sources) without interfering with the attainment and maintenance of any national ambient air quality standard within the period permitted in this section. If the Administrator determines that any such plan can be revised, he shall notify the State that a plan revision may be submitted by the State. Any plan revision which is submitted by the State shall, after public notice and opportunity for public hearing, be approved by the Administrator if the revision relates only to fuel burning stationary sources (or persons supplying fuel to such sources), and the plan as revised complies with paragraph (2) of this subsection. The Administrator shall approve or disapprove any revision no later than three months after its submission.

(C) Neither the State, in the case of a plan (or portion thereof) approved under this subsection, nor the Administrator, in the case of a plan (or portion thereof) promulgated under subsection (c), shall be required to revise an applicable implementation plan because one or more exemptions under section 118 [42 USCS § 7418] (relating to Federal facilities), enforcement orders under section 113(d), suspensions under section 110(f) or (g) [subsecs. (f) or (g) of this section] (relating to temporary energy or economic authority), orders

under section 119 [42 USCS § 7419] (relating to primary nonferrous smelters), or extensions of compliance in decrees entered under section 113(e) (relating to iron- and steel-producing operations) have been granted, if such plan would have met the requirements of this section if no such exemptions, orders, or extensions had been granted.

(4) [Repealed]

(5)

(A)

(i) Any State may include in a State implementation plan, but the Administrator may not require as a condition of approval of such plan under this section, any indirect source review program. The Administrator may approve and enforce, as part of an applicable implementation plan, an indirect source review program which the State chooses to adopt and submit as part of its plan.

(ii) Except as provided in subparagraph (B), no plan promulgated by the Administrator shall include any indirect source review program for any air quality control region, or portion thereof.

(iii) Any State may revise an applicable implementation plan approved under section 110(a) [42 USCS § 7410(a)] to suspend or revoke any such program included in such plan, provided that such plan meets the requirements of this section.

(B) The Administrator shall have the authority to promulgate, implement and enforce regulations under section 110(c) [42 USCS § 7410(c)] respecting indirect source review programs which apply only to federally assisted highways, airports, and other major federally assisted indirect sources and federally owned or operated indirect sources.

(C) For purposes of this paragraph, the term “indirect source” means a facility, building, structure, installation, real property, road, or highway which attracts, or may attract, mobile sources of pollution. Such term includes parking lots, parking garages, and other facilities subject to any measure for management of parking supply (within the meaning of section 110(c)(2)(D)(ii) [42 USCS § 7410(c)(2)(D)(ii)]), including regulation of existing off-street parking but such term does not include new or existing on-street parking. Direct emissions sources or facilities at, within, or associated with, any indirect source shall not be deemed indirect sources for the purpose of this paragraph.

(D) For purposes of this paragraph the term “indirect source review program” means the facility-by-facility review of indirect sources of air pollution, including such measures as are necessary to assure, or assist in assuring, that a new or modified indirect source will not attract mobile sources of air pollution, the emissions from which would cause or contribute to air pollution concentrations—

(i) exceeding any national primary ambient air quality standard for a mobile source-related air pollutant after the primary standard attainment date, or

(ii) preventing maintenance of any such standard after such date.

(E) For purposes of this paragraph and paragraph (2)(B), the term “transportation control measure” does not include any measure which is an “indirect source review program”.

(6) No State plan shall be treated as meeting the requirements of this section unless such plan provides that in the case of any source which uses a supplemental, or intermittent control system for purposes of meeting the requirements of an order under section 113(d) or section 119 (relating to primary nonferrous smelter orders) [42 USCS § 7419], the owner or operator of such source may not temporarily reduce the pay of any employee by reason of the use of such supplemental or intermittent or other dispersion dependent control system.

(b) Extension of period for submission of plans. The Administrator may, wherever he determines necessary, extend the period for submission of any plan or portion thereof which implements a national secondary ambient air quality standard for a period not to exceed 18 months from the date otherwise required for submission of such plan.

(c) Preparation and publication by Administrator of proposed regulations setting forth implementation plan; transportation

regulations study and report; parking surcharge; suspension authority; plan implementation.

(1) The Administrator shall promulgate a Federal implementation plan at any time within 2 years after the Administrator—

(A) finds that a State has failed to make a required submission or finds that the plan or plan revision submitted by the State does not satisfy the minimum criteria established under section 110(k)(1)(A) [42 USCS § 7410(k)(1)(A)], or

(B) disapproves a State implementation plan submission in whole or in part,

unless the State corrects the deficiency, and the Administrator approves the plan or plan revision, before the Administrator promulgates such Federal implementation plan.

(2)

(A) [Repealed]

(B) No parking surcharge regulation may be required by the Administrator under paragraph (1) of this subsection as a part of an applicable implementation plan. All parking surcharge regulations previously required by the Administrator shall be void upon the date of enactment of this subparagraph. This subparagraph shall not prevent the Administrator from approving parking surcharges if they are adopted and submitted by a State as part of an applicable

implementation plan. The Administrator may not condition approval of any implementation plan submitted by a State on such plan's including a parking surcharge regulation.

(C) [Repealed]

(D) For purposes of this paragraph—

(i) The term “parking surcharge regulation” means a regulation imposing or requiring the imposition of any tax, surcharge, fee, or other charge on parking spaces, or any other area used for the temporary storage of motor vehicles.

(ii) The term “management of parking supply” shall include any requirement providing that any new facility containing a given number of parking spaces shall receive a permit or other prior approval, issuance of which is to be conditioned on air quality considerations.

(iii) The term “preferential bus/carpool lane” shall include any requirement for the setting aside of one or more lanes of a street or highway on a permanent or temporary basis for the exclusive use of buses or carpools, or both.

(E) No standard, plan, or requirement, relating to management of parking supply or preferential bus/carpool lanes shall be promulgated after the date of enactment of this paragraph [enacted June 22, 1974] by the Administrator pursuant to this section, unless such

promulgation has been subjected to at least one public hearing which has been held in the area affected and for which reasonable notice has been given in such area. If substantial changes are made following public hearings, one or more additional hearings shall be held in such area after such notice.

(3) Upon application of the chief executive officer of any general purpose unit of local government, if the Administrator determines that such unit has adequate authority under State or local law, the Administrator may delegate to such unit the authority to implement and enforce within the jurisdiction of such unit any part of a plan promulgated under this subsection. Nothing in this paragraph shall prevent the Administrator from implementing or enforcing any applicable provision of a plan promulgated under this subsection.

(4) [Repealed]

(5)

(A) Any measure in an applicable implementation plan which requires a toll or other charge for the use of a bridge located entirely within one city shall be eliminated from such plan by the Administrator upon application by the Governor of the State, which application shall include a certification by the Governor that he will revise such plan in accordance with subparagraph (B).

(B) In the case of any applicable implementation plan with respect to which a measure has been eliminated under subparagraph (A), such plan shall, not later than one year after the date of the enactment of this subparagraph [enacted Aug. 7, 1977], be revised to include comprehensive measures to:

(i) establish, expand, or improve public transportation measures to meet basic transportation needs, as expeditiously as is practicable; and

(ii) implement transportation control measures necessary to attain and maintain national ambient air quality standards,

and such revised plan shall, for the purpose of implementing such comprehensive public transportation measures, include requirements to use (insofar as is necessary) Federal grants, State or local funds, or any combination of such grants and funds as may be consistent with the terms of the legislation providing such grants and funds. Such measures shall, as a substitute for the tolls or charges eliminated under subparagraph (A), provide for emissions reductions equivalent to the reductions which may reasonably be expected to be achieved through the use of the tolls or charges eliminated.

(C) Any revision of an implementation plan for purposes of meeting the requirements of subparagraph (B) shall be submitted in

coordination with any plan revision required under part D [42 USCS §§ 7501 et seq.].

(d), (e) [Repealed]

(f) National or regional energy emergencies; determination by President.

(1) Upon application by the owner or operator of a fuel burning stationary source, and after notice and opportunity for public hearing, the Governor of the State in which such source is located may petition the President to determine that a national or regional energy emergency exists of such severity that—

(A) a temporary suspension of any part of the applicable implementation plan or of any requirement under section 411 (concerning excess emissions penalties or offsets) of title IV of the Act [42 USCS § 7651j] may be necessary, and

(B) other means of responding to the energy emergency may be inadequate.

Such determination shall not be delegable by the President to any other person. If the President determines that a national or regional energy emergency of such severity exists, a temporary emergency suspension of any part of an applicable implementation plan or of any requirement under section 411 (concerning excess emissions penalties or offsets) of title IV of the Act [42 USCS § 7651j] adopted by the State may be issued

by the Governor of any State covered by the President's determination under the condition specified in paragraph (2) and may take effect immediately.

(2) A temporary emergency suspension under this subsection shall be issued to a source only if the Governor of such State finds that—

(A) there exists in the vicinity of such source a temporary energy emergency involving high levels of unemployment or loss of necessary energy supplies for residential dwellings; and

(B) such unemployment or loss can be totally or partially alleviated by such emergency suspension.

Not more than one such suspension may be issued for any source on the basis of the same set of circumstances or on the basis of the same emergency.

(3) A temporary emergency suspension issued by a Governor under this subsection shall remain in effect for a maximum of four months or such lesser period as may be specified in a disapproval order of the Administrator, if any. The Administrator may disapprove such suspension if he determines that it does not meet the requirements of paragraph (2).

(4) This subsection shall not apply in the case of a plan provision or requirement promulgated by the Administrator under subsection (c) of

this section, but in any such case the President may grant a temporary emergency suspension for a four month period of any such provision or requirement if he makes the determinations and findings specified in paragraphs (1) and (2).

(5) The Governor may include in any temporary emergency suspension issued under this subsection a provision delaying for a period identical to the period of such suspension any compliance schedule (or increment of progress) to which such source is subject under section 119, as in effect before the date of the enactment of this paragraph [enacted Aug. 7, 1977] or section 113(d) of this Act, upon a finding that such source is unable to comply with such schedule (or increment) solely because of the conditions on the basis of which a suspension was issued under this subsection.

(g) Governor's authority to issue temporary emergency suspensions.

(1) In the case of any State which has adopted and submitted to the Administrator a proposed plan revision which the State determines—

(A) meets the requirements of this section, and

(B) is necessary (i) to prevent the closing for one year or more of any source of air pollution, and (ii) to prevent substantial increases in unemployment which would result from such closing, and

which the Administrator has not approved or disapproved under this section within 12 months of submission of the proposed plan revision, the Governor may issue a temporary emergency suspension of the part of the applicable implementation plan for such State which is proposed to be revised with respect to such source. The determination under subparagraph (B) may not be made with respect to a source which would close without regard to whether or not the proposed plan revision is approved.

(2) A temporary emergency suspension issued by a Governor under this subsection shall remain in effect for a maximum of four months or such lesser period as may be specified in a disapproval order of the Administrator. The Administrator may disapprove such suspension if he determines that it does not meet the requirements of this subsection.

(3) The Governor may include in any temporary emergency suspension issued under this subsection a provision delaying for a period identical to the period of such suspension any compliance schedule (or increment of progress) to which such source is subject under section 119 as in effect before the date of the enactment of this paragraph [enacted Aug. 7, 1977], or under section 113(d) upon a finding that such source is unable to comply with such schedule (or increment) solely because of the conditions on the basis of which a suspension was issued under this subsection.

(h) Publication of comprehensive document for each State setting forth requirements of applicable implementation plan.

(1) Not later than 5 years after the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], and every 3 years thereafter, the Administrator shall assemble and publish a comprehensive document for each State setting forth all requirements of the applicable implementation plan for such State and shall publish notice in the Federal Register of the availability of such documents.

(2) The Administrator may promulgate such regulations as may be reasonably necessary to carry out the purpose of this subsection.

(i) Modification of requirements prohibited. Except for a primary nonferrous smelter order under section 119 [42 USCS § 7419], a suspension under section 110(f) or (g) [subsec. (f) or (g) of this section] (relating to emergency suspensions), an exemption under section 118 [42 USCS § 7418] (relating to certain Federal facilities), an order under section 113(d) (relating to compliance orders), a plan promulgation under section 110(c) [subsec. (c) of this section], or a plan revision under section 110(a)(3) [subsec. (a)(3) of this section], no order, suspension, plan revision, or other action modifying any requirement of an applicable implementation plan may be taken with respect to any stationary source by the State or by the Administrator.

(j) Technological systems of continuous emission reduction on new or modified stationary sources; compliance with performance standards.

As a condition for issuance of any permit required under this title, the owner or operator of each new or modified stationary source which is required to obtain such a permit must show to the satisfaction of the permitting authority that the technological system of continuous emission reduction which is to be used will enable such source to comply with the standards of performance which are to apply to such source and that the construction or modification and operation of such source will be in compliance with all other requirements of this Act.

(k) Environmental Protection Agency action on plan submissions.

(1) Completeness of plan submissions.

(A) Completeness criteria. Within 9 months after the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], the Administrator shall promulgate minimum criteria that any plan submission must meet before the Administrator is required to act on such submission under this subsection. The criteria shall be limited to the information necessary to enable the Administrator to determine whether the plan submission complies with the provisions of this Act.

(B) Completeness finding. Within 60 days of the Administrator's receipt of a plan or plan revision, but no later than 6 months after the date, if any, by which a State is required to submit the plan or revision, the Administrator shall determine whether the minimum

criteria established pursuant to subparagraph (A) have been met. Any plan or plan revision that a State submits to the Administrator, and that has not been determined by the Administrator (by the date 6 months after receipt of the submission) to have failed to meet the minimum criteria established pursuant to subparagraph (A), shall on that date be deemed by operation of law to meet such minimum criteria.

(C) Effect of finding of incompleteness. Where the Administrator determines that a plan submission (or part thereof) does not meet the minimum criteria established pursuant to subparagraph (A), the State shall be treated as not having made the submission (or, in the Administrator's discretion, part thereof).

(2) Deadline for action. Within 12 months of a determination by the Administrator (or a determination deemed by operation of law) under paragraph (1) that a State has submitted a plan or plan revision (or, in the Administrator's discretion, part thereof) that meets the minimum criteria established pursuant to paragraph (1), if applicable (or, if those criteria are not applicable, within 12 months of submission of the plan or revision), the Administrator shall act on the submission in accordance with paragraph (3).

(3) Full and partial approval and disapproval. In the case of any submittal on which the Administrator is required to act under paragraph

(2), the Administrator shall approve such submittal as a whole if it meets all of the applicable requirements of this Act. If a portion of the plan revision meets all the applicable requirements of this Act, the Administrator may approve the plan revision in part and disapprove the plan revision in part. The plan revision shall not be treated as meeting the requirements of this Act until the Administrator approves the entire plan revision as complying with the applicable requirements of this Act.

(4) Conditional approval. The Administrator may approve a plan revision based on a commitment of the State to adopt specific enforceable measures by a date certain, but not later than 1 year after the date of approval of the plan revision. Any such conditional approval shall be treated as a disapproval if the State fails to comply with such commitment.

(5) Calls for plan revisions. Whenever the Administrator finds that the applicable implementation plan for any area is substantially inadequate to attain or maintain the relevant national ambient air quality standard, to mitigate adequately the interstate pollutant transport described in section 176A or section 184 [42 USCS § 7506a or § 7511c], or to otherwise comply with any requirement of this Act, the Administrator shall require the State to revise the plan as necessary to correct such inadequacies. The Administrator shall notify the State of the inadequacies, and may establish reasonable deadlines (not to exceed 18 months after the date of

such notice) for the submission of such plan revisions. Such findings and notice shall be public. Any finding under this paragraph shall, to the extent the Administrator deems appropriate, subject the State to the requirements of this Act to which the State was subject when it developed and submitted the plan for which such finding was made, except that the Administrator may adjust any dates applicable under such requirements as appropriate (except that the Administrator may not adjust any attainment date prescribed under part D [42 USCS §§ 7501 et seq.], unless such date has elapsed).

(6) Corrections. Whenever the Administrator determines that the Administrator's action approving, disapproving, or promulgating any plan or plan revision (or part thereof), area designation, redesignation, classification, or reclassification was in error, the Administrator may in the same manner as the approval, disapproval, or promulgation revise such action as appropriate without requiring any further submission from the State. Such determination and the basis thereof shall be provided to the State and public.

(I) Plan revisions. Each revision to an implementation plan submitted by a State under this Act shall be adopted by such State after reasonable notice and public hearing. The Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning

attainment and reasonable further progress (as defined in section 171 [42 USCS § 7501]), or any other applicable requirement of this Act.

(m) Sanctions. The Administrator may apply any of the sanctions listed in section 179(b) [42 USCS § 7509(b)] at any time (or at any time after) the Administrator makes a finding, disapproval, or determination under paragraphs (1) through (4), respectively, of section 179(a) [42 USCS § 7509(a)] in relation to any plan or plan item (as that term is defined by the Administrator) required under this Act, with respect to any portion of the State the Administrator determines reasonable and appropriate, for the purpose of ensuring that the requirements of this Act relating to such plan or plan item are met. The Administrator shall, by rule, establish criteria for exercising his authority under the previous sentence with respect to any deficiency referred to in section 179(a) [42 USCS § 7509(a)] to ensure that, during the 24-month period following the finding, disapproval, or determination referred to in section 179(a) [42 USCS § 7509(a)], such sanctions are not applied on a statewide basis where one or more political subdivisions covered by the applicable implementation plan are principally responsible for such deficiency.

(n) Savings clauses.

(1) Existing plan provisions. Any provision of any applicable implementation plan that was approved or promulgated by the Administrator pursuant to this section as in effect before the date of the

enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990] shall remain in effect as part of such applicable implementation plan, except to the extent that a revision to such provision is approved or promulgated by the Administrator pursuant to this Act.

(2) Attainment dates. For any area not designated nonattainment, any plan or plan revision submitted or required to be submitted by a State—

(A) in response to the promulgation or revision of a national primary ambient air quality standard in effect on the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], or

(B) in response to a finding of substantial inadequacy under subsection (a)(2) (as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990) [enacted Nov. 15, 1990],

shall provide for attainment of the national primary ambient air quality standards within 3 years of the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990] or within 5 years of issuance of such finding of substantial inadequacy, whichever is later.

(3) Retention of construction moratorium in certain areas. In the case of an area to which, immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], the prohibition on construction or modification of major stationary sources prescribed in subsection (a)(2)(I) (as in effect immediately before the

date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) applied by virtue of a finding of the Administrator that the State containing such area had not submitted an implementation plan meeting the requirements of section 172(b)(6) [42 USCS § 7502(b)(6)] (relating to establishment of a permit program) (as in effect immediately before the date of enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) or 172(a)(1) [42 USCS § 7502(a)(1)] (to the extent such requirements relate to provision for attainment of the primary national ambient air quality standard for sulfur oxides by December 31, 1982) as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], no major stationary source of the relevant air pollutant or pollutants shall be constructed or modified in such area until the Administrator finds that the plan for such area meets the applicable requirements of section 172(c)(5) [42 USCS § 7502(c)(5)] (relating to permit programs) or subpart 5 of part D [42 USCS §§ 7514 et seq.] (relating to attainment of the primary national ambient air quality standard for sulfur dioxide), respectively.

(o) Indian tribes. If an Indian tribe submits an implementation plan to the Administrator pursuant to section 301(d) [42 USCS § 7601(d)], the plan shall be reviewed in accordance with the provisions for review set forth in this section for State plans, except as otherwise provided by regulation promulgated pursuant to section 301(d)(2) [42 USCS § 7601(d)(2)]. When

such plan becomes effective in accordance with the regulations promulgated under section 301(d) [42 USCS § 7601(d)], the plan shall become applicable to all areas (except as expressly provided otherwise in the plan) located within the exterior boundaries of the reservation, notwithstanding the issuance of any patent and including rights-of-way running through the reservation.

(p) Reports. Any State shall submit, according to such schedule as the Administrator may prescribe, such reports as the Administrator may require relating to emission reductions, vehicle miles traveled, congestion levels, and any other information the Administrator may deem necessary to assess the development[,] effectiveness, need for revision, or implementation of any plan or plan revision required under this Act.

42 USCS § 7475

§ 7475. Preconstruction requirements

(a) Major emitting facilities on which construction is commenced. No major emitting facility on which construction is commenced after the date of the enactment of this part [enacted Aug. 7, 1977], may be constructed in any area to which this part [42 USCS §§ 7470 et seq.] applies unless—

(1) a permit has been issued for such proposed facility in accordance with this part [42 USCS §§ 7470 et seq.] setting forth emission limitations for such facility which conform to the requirements of this part [42 USCS §§ 7470 et seq.];

(2) the proposed permit has been subject to a review in accordance with this section, the required analysis has been conducted in accordance with regulations promulgated by the Administrator, and a public hearing has been held with opportunity for interested persons including representatives of the Administrator to appear and submit written or oral presentations on the air quality impact of such source, alternatives thereto, control technology requirements, and other appropriate considerations;

(3) the owner or operator of such facility demonstrates, as required pursuant to section 110(j) [42 USCS § 7410(j)], that emissions from construction or operation of such facility will not cause, or contribute to, air pollution in excess of any (A) maximum allowable increase or

maximum allowable concentration for any pollutant in any area to which this part applies more than one time per year, (B) national ambient air quality standard in any air quality control region, or (C) any other applicable emission standard or standard of performance under this Act;

(4) the proposed facility is subject to the best available control technology for each pollutant subject to regulation under this Act emitted from, or which results from, such facility;

(5) the provisions of subsection (d) with respect to protection of class I areas have been complied with for such facility;

(6) there has been an analysis of any air quality impacts projected for the area as a result of growth associated with such facility;

(7) the person who owns or operates, or proposes to own or operate, a major emitting facility for which a permit is required under this part [42 USCS §§ 7470 et seq.] agrees to conduct such monitoring as may be necessary to determine the effect which emissions from any such facility may have, or is having, on air quality in any area which may be affected by emissions from such source; and

(8) in the case of a source which proposes to construct in a class III area, emissions from which would cause or contribute to exceeding the maximum allowable increments applicable in a class II area and where no standard under section 111 of this Act [42 USCS § 7411] has been promulgated subsequent to enactment of the Clean Air Act Amendments

of 1977 [enacted Aug. 7, 1977], for such source category, the Administrator has approved the determination of best available technology as set forth in the permit.

42 USCS § 7502**§ 7502. Nonattainment plan provisions in general****(a) Classifications and attainment dates.****(1) Classifications.**

(A) On or after the date the Administrator promulgates the designation of an area as a nonattainment area pursuant to section 107(d) [42 USCS § 7407(d)] with respect to any national ambient air quality standard (or any revised standard, including a revision of any standard in effect on the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]), the Administrator may classify the area for the purpose of applying an attainment date pursuant to paragraph (2), and for other purposes. In determining the appropriate classification, if any, for a nonattainment area, the Administrator may consider such factors as the severity of nonattainment in such area and the availability and feasibility of the pollution control measures that the Administrator believes may be necessary to provide for attainment of such standard in such area.

(B) The Administrator shall publish a notice in the Federal Register announcing each classification under subparagraph (A), except the Administrator shall provide an opportunity for at least 30 days for written comment. Such classification shall not be subject to the provisions of sections 553 through 557 of title 5 of the United States

Code (concerning notice and comment) and shall not be subject to judicial review until the Administrator takes final action under subsection (k) or (l) of section 110 [42 USCS § 7410(k) or (l)] (concerning action on plan submissions) or section 179 [42 USCS § 7509] (concerning sanctions) with respect to any plan submissions required by virtue of such classification.

(C) This paragraph shall not apply with respect to nonattainment areas for which classifications are specifically provided under other provisions of this part [42 USCS §§ 7501 et seq.].

(2) Attainment dates for nonattainment areas.

(A) The attainment date for an area designated nonattainment with respect to a national primary ambient air quality standard shall be the date by which attainment can be achieved as expeditiously as practicable, but no later than 5 years from the date such area was designated nonattainment under section 107(d) [42 USCS § 7407(d)], except that the Administrator may extend the attainment date to the extent the Administrator determines appropriate, for a period no greater than 10 years from the date of designation as nonattainment, considering the severity of nonattainment and the availability and feasibility of pollution control measures.

(B) The attainment date for an area designated nonattainment with respect to a secondary national ambient air quality standard shall be

the date by which attainment can be achieved as expeditiously as practicable after the date such area was designated nonattainment under section 107(d) [42 USCS § 7407(d)].

(C) Upon application by any State, the Administrator may extend for 1 additional year (hereinafter referred to as the “Extension Year”) the attainment date determined by the Administrator under subparagraph (A) or (B) if—

- (i) the State has complied with all requirements and commitments pertaining to the area in the applicable implementation plan, and
- (ii) in accordance with guidance published by the Administrator, no more than a minimal number of exceedances of the relevant national ambient air quality standard has occurred in the area in the year preceding the Extension Year.

No more than 2 one-year extensions may be issued under this subparagraph for a single nonattainment area.

(D) This paragraph shall not apply with respect to nonattainment areas for which attainment dates are specifically provided under other provisions of this part [42 USCS §§ 7501 et seq.].

(b) Schedule for plan submissions. At the time the Administrator promulgates the designation of an area as nonattainment with respect to a national ambient air quality standard under section 107(d) [42 USCS §

7407(d)], the Administrator shall establish a schedule according to which the State containing such area shall submit a plan or plan revision (including the plan items) meeting the applicable requirements of subsection (c) and section 110(a)(2) [42 USCS § 7410(a)(2)]. Such schedule shall at a minimum, include a date or dates, extending no later than 3 years from the date of the nonattainment designation, for the submission of a plan or plan revision (including the plan items) meeting the applicable requirements of subsection (c) and section 110(a)(2) [42 USCS § 7410(a)(2)].

(c) Nonattainment plan provisions. The plan provisions (including plan items) required to be submitted under this part [42 USCS §§ 7501 et seq.] shall comply with each of the following:

(1) In general. Such plan provisions shall provide for the implementation of all reasonably available control measures as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology) and shall provide for attainment of the national primary ambient air quality standards.

(2) RFP. Such plan provisions shall require reasonable further progress.

(3) Inventory. Such plan provisions shall include a comprehensive, accurate, current inventory of actual emissions from all sources of the relevant pollutant or pollutants in such area, including such periodic

revisions as the Administrator may determine necessary to assure that the requirements of this part [42 USCS §§ 7501 et seq.] are met.

(4) Identification and quantification. Such plan provisions shall expressly identify and quantify the emissions, if any, of any such pollutant or pollutants which will be allowed, in accordance with section 173(a)(1)(B) [42 USCS § 7503(a)(1)(B)], from the construction and operation of major new or modified stationary sources in each such area. The plan shall demonstrate to the satisfaction of the Administrator that the emissions quantified for this purpose will be consistent with the achievement of reasonable further progress and will not interfere with attainment of the applicable national ambient air quality standard by the applicable attainment date.

(5) Permits for new and modified major stationary sources. Such plan provisions shall require permits for the construction and operation of new or modified major stationary sources anywhere in the nonattainment area, in accordance with section 173 [42 USCS § 7503].

(6) Other measures. Such plan provisions shall include enforceable emission limitations, and such other control measures, means or techniques (including economic incentives such as fees, marketable permits, and auctions of emission rights), as well as schedules and timetables for compliance, as may be necessary or appropriate to provide

for attainment of such standard in such area by the applicable attainment date specified in this part [42 USCS §§ 7501 et seq.].

(7) Compliance with section 110(a)(2). Such plan provisions shall also meet the applicable provisions of section 110(a)(2) [42 USCS § 7410(a)(2)].

(8) Equivalent techniques. Upon application by any State, the Administrator may allow the use of equivalent modeling, emission inventory, and planning procedures, unless the Administrator determines that the proposed techniques are, in the aggregate, less effective than the methods specified by the Administrator.

(9) Contingency measures. Such plan shall provide for the implementation of specific measures to be undertaken if the area fails to make reasonable further progress, or to attain the national primary ambient air quality standard by the attainment date applicable under this part [42 USCS §§ 7501 et seq.]. Such measures shall be included in the plan revision as contingency measures to take effect in any such case without further action by the State or the Administrator.

(d) Plan revisions required in response to finding of plan inadequacy.

Any plan revision for a nonattainment area which is required to be submitted in response to a finding by the Administrator pursuant to section 110(k)(5) [42 USCS § 7410(k)(5)] (relating to calls for plan revisions) must correct the plan deficiency (or deficiencies) specified by the Administrator and meet all

other applicable plan requirements of section 110 and this part [42 USCS § 7410 and §§ 7501 et seq.]. The Administrator may reasonably adjust the dates otherwise applicable under such requirements to such revision (except for attainment dates that have not yet elapsed), to the extent necessary to achieve a consistent application of such requirements. In order to facilitate submittal by the States of adequate and approvable plans consistent with the applicable requirements of this Act, the Administrator shall, as appropriate and from time to time, issue written guidelines, interpretations, and information to the States which shall be available to the public, taking into consideration any such guidelines, interpretations, or information provided before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990].

(e) Future modification of standard. If the Administrator relaxes a national primary ambient air quality standard after the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990], the Administrator shall, within 12 months after the relaxation, promulgate requirements applicable to all areas which have not attained that standard as of the date of such relaxation. Such requirements shall provide for controls which are not less stringent than the controls applicable to areas designated nonattainment before such relaxation.

42 USCS § 7503

§ 7503. Permit requirements

(a) In general. The permit program required by section 172(b)(6) shall provide that permits to construct and operate may be issued if—

(1) in accordance with regulations issued by the Administrator for the determination of baseline emissions in a manner consistent with the assumptions underlying the applicable implementation plan approved under section 110 and this part [42 USCS § 7410 and §§ 7501 et seq.], the permitting agency determines that—

(A) by the time the source is to commence operation, sufficient offsetting emissions reductions have been obtained, such that total allowable emissions from existing sources in the region, from new or modified sources which are not major emitting facilities, and from the proposed source will be sufficiently less than total emissions from existing sources (as determined in accordance with the regulations under this paragraph) prior to the application for such permit to construct or modify so as to represent (when considered together with the plan provisions required under section 172 [42 USCS § 7502]) reasonable further progress (as defined in section 171 [42 USCS § 7501]); or

(B) in the case of a new or modified major stationary source which is located in a zone (within the nonattainment area) identified by the

Administrator, in consultation with the Secretary of Housing and Urban Development, as a zone to which economic development should be targeted, that emissions of such pollutant resulting from the proposed new or modified major stationary source will not cause or contribute to emissions levels which exceed the allowance permitted for such pollutant for such area from new or modified major stationary sources under section 172(c) [42 USCS § 7502(c)];

(2) the proposed source is required to comply with the lowest achievable emission rate;

(3) the owner or operator of the proposed new or modified source has demonstrated that all major stationary sources owned or operated by such person (or by any entity controlling, controlled by, or under common control with such person) in such State are subject to emission limitations and are in compliance, or on a schedule for compliance, with all applicable emission limitations and standards under this Act; [and]

(4) the Administrator has not determined that the applicable implementation plan is not being adequately implemented for the nonattainment area in which the proposed source is to be constructed or modified in accordance with the requirements of this part [42 USCS §§ 7501 et seq.]; and

(5) an analysis of alternative sites, sizes, production processes, and environmental control techniques for such proposed source demonstrates

that benefits of the proposed source significantly outweigh the environmental and social costs imposed as a result of its location, construction, or modification.

Any emission reductions required as a precondition of the issuance of a permit under paragraph (1) shall be federally enforceable before such permit may be issued.

(b) Prohibition on use of old growth allowances. Any growth allowance included in an applicable implementation plan to meet the requirements of section 172(b)(5) [42 USCS § 7502(b)(5)] (as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) shall not be valid for use in any area that received or receives a notice under section 110(a)(2)(H)(ii) [42 USCS § 7410(a)(2)(H)(ii)] (as in effect immediately before the date of the enactment of the Clean Air Act Amendments of 1990 [enacted Nov. 15, 1990]) or under section 110(k)(1) [42 USCS § 7410(k)(1)] that its applicable implementation plan containing such allowance is substantially inadequate.

(c) Offsets.

(1) The owner or operator of a new or modified major stationary source may comply with any offset requirement in effect under this part [42 USCS §§ 7501 et seq.] for increased emissions of any air pollutant only by obtaining emission reductions of such air pollutant from the same source or other sources in the same nonattainment area, except that the

State may allow the owner or operator of a source to obtain such emission reductions in another nonattainment area if (A) the other area has an equal or higher nonattainment classification than the area in which the source is located and (B) emissions from such other area contribute to a violation of the national ambient air quality standard in the nonattainment area in which the source is located. Such emission reductions shall be, by the time a new or modified source commences operation, in effect and enforceable and shall assure that the total tonnage of increased emissions of the air pollutant from the new or modified source shall be offset by an equal or greater reduction, as applicable, in the actual emissions of such air pollutant from the same or other sources in the area.

(2) Emission reductions otherwise required by this Act shall not be creditable as emissions reductions for purposes of any such offset requirement. Incidental emission reductions which are not otherwise required by this Act shall be creditable as emission reductions for such purposes if such emission reductions meet the requirements of paragraph (1).

42 USCS § 7602**§ 7602. Definitions**

When used in this Act—

(a) The term “Administrator” means the Administrator of the Environmental Protection Agency.

(b) The term “air pollution control agency” means any of the following:

(1) A single State agency designated by the Governor of that State as the official State air pollution control agency for purposes of this Act.

(2) An agency established by two or more States and having substantial powers or duties pertaining to the prevention and control of air pollution.

(3) A city, county, or other local government health authority, or, in the case of any city, county, or other local government in which there is an agency other than the health authority charged with responsibility for enforcing ordinances or laws relating to the prevention and control of air pollution, such other agency.

(4) An agency of two or more municipalities located in the same State or in different States and having substantial powers or duties pertaining to the prevention and control of air pollution.

(5) An agency of an Indian tribe.

(c) The term “interstate air pollution control agency” means—

(1) an air pollution control agency established by two or more States, or

(2) an air pollution control agency of two or more municipalities located in different States.

(d) The term “State” means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa and includes the Commonwealth of the Northern Mariana Islands.

(e) The term “person” includes an individual, corporation, partnership, association, State, municipality, political subdivision of a State, and any agency, department, or instrumentality of the United States and any officer, agent, or employee thereof.

(f) The term “municipality” means a city, town, borough, county, parish, district, or other public body created by or pursuant to State law.

(g) The term “air pollutant” means any air pollution agent or combination of such agents, including any physical, chemical, biological, radioactive (including source material, special nuclear material, and byproduct material) substance or matter which is emitted into or otherwise enters the ambient air. Such term includes any precursors to the formation of any air pollutant, to the extent the Administrator has identified such precursor or precursors for the particular purpose for which the term “air pollutant” is used.

(h) All language referring to effects on welfare includes, but is not limited to, effects on soils, waters, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and

hazards to transportation, as well as effects on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants.

42 USCS § 7607

§ 7607. Administrative proceedings and judicial review

(a) Administrative subpoenas; confidentiality; witnesses. In connection with any determination under section 110(f) [42 USCS § 7410(f)], or for purposes of obtaining information under section 202(b)(4) or 211(c)(3) [42 USCS § 7521(b)(4) or 7545(c)(3)], any investigation, monitoring, reporting requirement, entry, compliance inspection, or administrative enforcement proceeding under the [this] Act (including but not limited to section 113, section 114, section 120, section 129, section 167, section 205, section 206, section 208, section 303, or section 306 [42 USCS § 7413, 7414, 7420, 7429, 7477, 7524, 7525, 7542, 7603, or 7606][,], the Administrator may issue subpoenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents, and he may administer oaths. Except for emission data, upon a showing satisfactory to the Administrator by such owner or operator that such papers, books, documents, or information or particular part thereof, if made public, would divulge trade secrets or secret processes of such owner or operator, the Administrator shall consider such record, report, or information or particular portion thereof confidential in accordance with the purposes of section 1905 of title 18 of the United States Code, except that such paper, book, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out this Act, to persons carrying out the National Academy of Sciences' study and investigation provided for in section 202(c) [42 USCS §

7521(c)], or when relevant in any proceeding under this Act. Witnesses summoned shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In case of contumacy or refusal to obey a subpoena served upon any person under this subparagraph, the district court of the United States for any district in which such person is found or resides or transacts business, upon application by the United States and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the Administrator to appear and produce papers, books, and documents before the Administrator, or both, and any failure to obey such order of the court may be punished by such court as a contempt thereof.

(b) Judicial review.

(1) A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quality standard, any emission standard or requirement under section 112 [42 USCS § 7412], any standard of performance or requirement under section 111 [42 USCS § 7411][,], any standard under section 202 [42 USCS § 7521] (other than a standard required to be prescribed under section 202(b)(1) [42 USCS § 7521(b)(1)]), any determination under section 202(b)(5) [42 USCS § 7521(b)(5)], any control or prohibition under section 211 [42 USCS § 7545], any standard under section 231 [42 USCS § 7571] any rule issued under section 113, 119, or under section 120 [42 USCS § 7413, 7419, or 7420], or any other nationally applicable regulations promulgated, or final action taken, by the

Administrator under this Act may be filed only in the United States Court of Appeals for the District of Columbia. A petition for review of the Administrator's action in approving or promulgating any implementation plan under section 110 or section 111(d) [42 USCS § 7410 or 7411(d)], any order under section 111(j) [42 USCS § 7411(j)], under section 112 [42 USCS § 7412],[,] under section 119 [42 USCS § 7419], or under section 120 [42 USCS § 7420], or his action under section 119(c)(2)(A), (B), or (C) (as in effect before the date of enactment of the Clean Air Act Amendments of 1977) or under regulations thereunder, or revising regulations for enhanced monitoring and compliance certification programs under section 114(a)(3) of this Act, or any other final action of the Administrator under this Act (including any denial or disapproval by the Administrator under title I [42 USCS §§ 7401 et seq.]) which is locally or regionally applicable may be filed only in the United States Court of Appeals for the appropriate circuit. Notwithstanding the preceding sentence a petition for review of any action referred to in such sentence may be filed only in the United States Court of Appeals for the District of Columbia if such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination. Any petition for review under this subsection shall be filed within sixty days from the date notice of such promulgation, approval, or action appears in the Federal Register, except that if such petition is based solely on grounds arising after such sixtieth day, then any petition for review

under this subsection shall be filed within sixty days after such grounds arise. The filing of a petition for reconsideration by the Administrator of any otherwise final rule or action shall not affect the finality of such rule or action for purposes of judicial review nor extend the time within which a petition for judicial review of such rule or action under this section may be filed, and shall not postpone the effectiveness of such rule or action.

(2) Action of the Administrator with respect to which review could have been obtained under paragraph (1) shall not be subject to judicial review in civil or criminal proceedings for enforcement. Where a final decision by the Administrator defers performance of any nondiscretionary statutory action to a later time, any person may challenge the deferral pursuant to paragraph (1).

(c) Additional evidence. In any judicial proceeding in which review is sought of a determination under this Act required to be made on the record after notice and opportunity for hearing, if any party applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, in such manner and upon such terms and conditions as [to] the court may deem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken and he shall

file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original determination, with the return of such additional evidence.

(d) Rulemaking.

(1) This subsection applies to—

(A) the promulgation or revision of any national ambient air quality standard under section 109 [42 USCS § 7409],

(B) the promulgation or revision of an implementation plan by the Administrator under section 110(c) [42 USCS § 7410(c)],

(C) the promulgation or revision of any standard of performance under section 111 [42 USCS § 7411], or emission standard or limitation under section 112(d) [42 USCS § 7412(d)], any standard under section 112(f) [42 USCS § 7412(f)], or any regulation under section 112(g)(1)(D) and (F) [42 USCS § 7412(g)(1)(D),(F)], or any regulation under section 112(m) or (n) [42 USCS § 7412(m) or (n)],

(D) the promulgation of any requirement for solid waste combustion under section 129 [42 USCS § 7429],

(E) the promulgation or revision of any regulation pertaining to any fuel or fuel additive under section 211 [42 USCS § 7545],

(F) the promulgation or revision of any aircraft emission standard under section 231 [42 USCS § 7571],

(G) the promulgation or revision of any regulation under title IV (relating to control of acid deposition),

(H) promulgation or revision of regulations pertaining to primary nonferrous smelter orders under section 119 [42 USCS § 7419] (but not including the granting or denying of any such order),

(I) promulgation or revision of regulations under title VI [42 USCS §§ 7671 et seq.] (relating to stratosphere and ozone protection),

(J) promulgation or revision of regulations under subtitle C of title I [42 USCS §§ 7470 et seq.] (relating to prevention of significant deterioration of air quality and protection of visibility),

(K) promulgation or revision of regulations under section 202 [42 USCS § 7521] and test procedures for new motor vehicles or engines under section 206 [42 USCS § 7525], and the revision of a standard under section 202(a)(3) [42 USCS § 7521(a)(3)],

(L) promulgation or revision of regulations for noncompliance penalties under section 120 [42 USCS § 7420],

(M) promulgation or revision of any regulations promulgated under section 207 [42 USCS § 7541] (relating to warranties and compliance by vehicles in actual use),

(N) action of the Administrator under section 126 [42 USCS § 7426] (relating to interstate pollution abatement),

(O) the promulgation or revision of any regulation pertaining to consumer and commercial products under section 183(e) [42 USCS § 7511b(e)],

(P) the promulgation or revision of any regulation pertaining to field citations under section 113(d)(3) [42 USCS § 7413(d)(3)],

(Q) the promulgation or revision of any regulation pertaining to urban buses or the clean-fuel vehicle, clean-fuel fleet, and clean fuel programs under part C of title II [42 USCS §§ 7581 et seq.],

(R) the promulgation or revision of any regulation pertaining to nonroad engines or nonroad vehicles under section 213 [42 USCS § 7547],

(S) the promulgation or revision of any regulation relating to motor vehicle compliance program fees under section 217 [42 USCS § 7552],

(T) the promulgation or revision of any regulation under title IV [42 USCS §§ 7641 et seq.] (relating to acid deposition),

(U) the promulgation or revision of any regulation under section 183(f) [42 USCS § 7511b(f)] pertaining to marine vessels, and

(V) such other actions as the Administrator may determine.

The provisions of section 553 through 557 and section 706 of title 5 of the United States Code shall not, except as expressly provided in this subsection, apply to

actions to which this subsection applies. This subsection shall not apply in the case of any rule or circumstance referred to in subparagraphs (A) or (B) of subsection 553(b) of title 5 of the United States Code.

(2) Not later than the date of proposal of any action to which this subsection applies, the Administrator shall establish a rulemaking docket for such action (hereinafter in this subsection referred to as a “rule”). Whenever a rule applies only within a particular State, a second (identical) docket shall be simultaneously established in the appropriate regional office of the Environmental Protection Agency.

(3) In the case of any rule to which this subsection applies, notice of proposed rulemaking shall be published in the Federal Register, as provided under section 553(b) of title 5, United States Code, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment (hereinafter referred to as the “comment period”). The notice of proposed rulemaking shall also state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The statement of basis and purpose shall include a summary of—

(A) the factual data on which the proposed rule is based;

(B) the methodology used in obtaining the data and in analyzing the data;

and

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 109(d) [42 USCS § 7409(d)] and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

(4)

(A) The rulemaking docket required under paragraph (2) shall be open for inspection by the public at reasonable times specified in the notice of proposed rulemaking. Any person may copy documents contained in the docket. The Administrator shall provide copying facilities which may be used at the expense of the person seeking copies, but the Administrator may waive or reduce such expenses in such instances as the public interest requires. Any person may request copies by mail if the person pays the expenses, including personnel costs to do the copying.

(B)

(i) Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket. The transcript of public hearings, if any, on the proposed rule shall also be included in the docket promptly upon receipt from the person who transcribed such hearings. All documents which become available after the proposed rule has been published and which the Administrator determines are of central relevance to the rulemaking shall be placed in the docket as soon as possible after their availability.

(ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

(5) In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) the Administrator shall give interested persons an opportunity for

the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (iii) a transcript shall be kept of any oral presentation; and (iv) the Administrator shall keep the record of such proceeding open for thirty days after completion of the proceeding to provide an opportunity for submission of rebuttal and supplementary information.

(6)

(A) The promulgated rule shall be accompanied by (i) a statement of basis and purpose like that referred to in paragraph (3) with respect to a proposed rule and (ii) an explanation of the reasons for any major changes in the promulgated rule from the proposed rule.

(B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.

(C) The promulgated rule may not be based (in part or whole) on any information or data which has not been placed in the docket as of the date of such promulgation.

(7)

(A) The record for judicial review shall consist exclusively of the material referred to in paragraph (3), clause (i) of paragraph (4)(B), and subparagraphs (A) and (B) of paragraph (6).

(B) Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b)). Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed during such reconsideration, however, by the Administrator or the court for a period not to exceed three months.

(8) The sole forum for challenging procedural determinations made by the Administrator under this subsection shall be in the United States court of appeals for the appropriate circuit (as provided in subsection (b)) at the time of the substantive review of the rule. No interlocutory appeals shall be permitted with respect to such procedural determinations. In reviewing alleged procedural errors,

the court may invalidate the rule only if the errors were so serious and related to matters of such central relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.

(9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; or

(D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of paragraph (7)(B) has been met, and (iii) the condition of the last sentence of paragraph (8) is met.

(10) Each statutory deadline for promulgation of rules to which this subsection applies which requires promulgation less than six months after date of proposal may be extended to not more than six months after date of proposal by the Administrator upon a determination that such extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of this subsection.

(11) The requirements of this subsection shall take effect with respect to any rule the proposal of which occurs after ninety days after the date of enactment of the Clean Air Act Amendments of 1977 [enacted Aug. 7, 1977].

(e) Other methods of judicial review not authorized. Nothing in this Act shall be construed to authorize judicial review of regulations or orders of the Administrator under this Act, except as provided in this section.

(f) Costs. In any judicial proceeding under this section, the court may award costs of litigation (including reasonable attorney and expert witness fees) whenever it determines that such award is appropriate.

(g) Stay, injunction, or similar relief in proceedings relating to noncompliance penalties. In any action respecting the promulgation of regulations under section 120 [42 USCS § 7420] or the administration or enforcement of section 120 [42 USCS § 7420] no court shall grant any stay, injunctive, or similar relief before final judgment by such court in such action.

(h) Public Participation. It is the intent of Congress that, consistent with the policy of the Administrative Procedures Act [5 USCS §§ 551 et seq.], the Administrator in promulgating any regulation under this Act, including a regulation subject to a deadline, shall ensure a reasonable period for public participation of at least 30 days, except as otherwise expressly provided in section [sections] 107(d), 172(a), 181(a) and (b), and 186(a) and (b) [42 USCS §§ 7407(d), 7502(a), 7511(a) and (b), 7512(a) and (b)].

40 CFR 51.160**§ 51.160 Legally enforceable procedures.**

(a) Each plan must set forth legally enforceable procedures that enable the State or local agency to determine whether the construction or modification of a facility, building, structure or installation, or combination of these will result in —

(1) A violation of applicable portions of the control strategy; or

(2) Interference with attainment or maintenance of a national standard in the State in which the proposed source (or modification) is located or in a neighboring State.

(b) Such procedures must include means by which the State or local agency responsible for final decisionmaking on an application for approval to construct or modify will prevent such construction or modification if —

(1) It will result in a violation of applicable portions of the control strategy; or

(2) It will interfere with the attainment or maintenance of a national standard.

(c) The procedures must provide for the submission, by the owner or operator of the building, facility, structure, or installation to be constructed or modified, of such information on —

(1) The nature and amounts of emissions to be emitted by it or emitted by associated mobile sources;

- (2) The location, design, construction, and operation of such facility, building, structure, or installation as may be necessary to permit the State or local agency to make the determination referred to in paragraph (a) of this section.
- (d) The procedures must provide that approval of any construction or modification must not affect the responsibility to the owner or operator to comply with applicable portions of the control strategy.
- (e) The procedures must identify types and sizes of facilities, buildings, structures, or installations which will be subject to review under this section. The plan must discuss the basis for determining which facilities will be subject to review.
- (f) The procedures must discuss the air quality data and the dispersion or other air quality modeling used to meet the requirements of this subpart.
- (1) All applications of air quality modeling involved in this subpart shall be based on the applicable models, data bases, and other requirements specified in appendix W of this part (Guideline on Air Quality Models).
- (2) Where an air quality model specified in appendix W of this part (Guideline on Air Quality Models) is inappropriate, the model may be modified or another model substituted. Such a modification or substitution of a model may be made on a case-by-case basis or, where appropriate, on a generic basis for a specific state program. Written approval of the Administrator must be obtained for any modification or

substitution. In addition, use of a modified or substituted model must be subject to notice and opportunity for public comment under procedures set forth in § 51.102.

50 CFR 402.02**§ 402.02 Definitions.**

Act means the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 et seq.

Action means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to:

- (a) actions intended to conserve listed species or their habitat;
- (b) the promulgation of regulations;
- (c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or
- (d) actions directly or indirectly causing modifications to the land, water, or air.

Action area means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.

Applicant refers to any person, as defined in section 3(13) of the Act, who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.

Biological assessment refers to the information prepared by or under the direction of the Federal agency concerning listed and proposed species and designated and proposed critical habitat that may be present in the action

area and the evaluation potential effects of the action on such species and habitat.

Biological opinion is the document that states the opinion of the Service as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

Conference is a process which involves informal discussions between a Federal agency and the Service under section 7(a)(4) of the Act regarding the impact of an action on proposed species or proposed critical habitat and recommendations to minimize or avoid the adverse effects.

Critical habitat refers to an area designated as critical habitat listed in 50 CFR parts 17 or 226.

Cumulative effects are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.

Designated non-Federal representative refers to a person designated by the Federal agency as its representative to conduct informal consultation and/or to prepare any biological assessment.

Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species. Director refers to the Assistant Administrator for Fisheries for the National Marine Fisheries Service, or his

or her authorized representative; or the Director of the U.S. Fish and Wildlife Service, or his or her authorized representative.

Director refers to the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration, or his authorized representative; or the Fish and Wildlife Service regional director, or his authorized representative, for the region where the action would be carried out.

Early consultation is a process requested by a Federal agency on behalf of a prospective applicant under section 7(a)(3) of the Act.

Effects of the action are all consequences to listed species or critical habitat that are caused by the proposed action, including the consequences of other activities that are caused by the proposed action but that are not part of the action. A consequence is caused by the proposed action if it would not occur but for the proposed action and it is reasonably certain to occur. Effects of the action may occur later in time and may include consequences occurring outside the immediate area involved in the action.

Environmental baseline refers to the condition of the listed species or its designated critical habitat in the action area, without the consequences to the listed species or designated critical habitat caused by the proposed action.

The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. The impacts to listed species or designated critical

habitat from Federal agency activities or existing Federal agency facilities that are not within the agency's discretion to modify are part of the environmental baseline.

Formal consultation is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.

Framework programmatic action means, for purposes of an incidental take statement, a Federal action that approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time, and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Incidental take refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant.

Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required.

Jeopardize the continued existence of means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably

the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.

Listed species means any species of fish, wildlife, or plant which has been determined to be endangered or threatened under section 4 of the Act. Listed species are found in 50 CFR 17.11-17.12.

Major construction activity is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment as referred to in the National Environmental Policy Act [NEPA, 42 U.S.C. 4332(2)(C)].

Mixed programmatic action means, for purposes of an incidental take statement, a Federal action that approves action(s) that will not be subject to further section 7 consultation, and also approves a framework for the development of future action(s) that are authorized, funded, or carried out at a later time and any take of a listed species would not occur unless and until those future action(s) are authorized, funded, or carried out and subject to further section 7 consultation.

Preliminary biological opinion refers to an opinion issued as a result of early consultation.

Programmatic consultation is a consultation addressing an agency's multiple actions on a program, region, or other basis. Programmatic consultations allow the Services to consult on the effects of programmatic actions such as:

- (1) Multiple similar, frequently occurring, or routine actions expected to be implemented in particular geographic areas; and

(2) A proposed program, plan, policy, or regulation providing a framework for future proposed actions.

Proposed critical habitat means habitat proposed in the FEDERAL REGISTER to be designated or revised as critical habitat under section 4 of the Act for any listed or proposed species.

Proposed species means any species of fish, wildlife, or plant that is proposed in the FEDERAL REGISTER to be listed under section 4 of the Act.

Reasonable and prudent alternatives refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

Reasonable and prudent measures refer to those actions the Director considers necessary or appropriate to minimize the impact of the incidental take on the species.

Recovery means improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.

Service means the U.S. Fish and Wildlife Service or the National Marine Fisheries Service, as appropriate.

50 CFR 402.03

§ 402.03 Applicability.

Section 7 and the requirements of this part apply to all actions in which there is discretionary Federal involvement or control.

50 CFR 402.13**§ 402.13 Informal consultation.**

(a) Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative, designed to assist the Federal agency in determining whether formal consultation or a conference is required.

(b) During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat.

(c) If during informal consultation it is determined by the Federal agency, with the written concurrence of the Service, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary.

(1) A written request for concurrence with a Federal agency's not likely to adversely affect determination shall include information similar to the types of information described for formal consultation at § 402.14(c)(1) sufficient for the Service to determine if it concurs.

(2) Upon receipt of a written request consistent with paragraph (c)(1) of this section, the Service shall provide written concurrence or non-concurrence with the Federal agency's determination within 60 days. The 60-day timeframe may be extended upon mutual consent of the Service,

the Federal agency, and the applicant (if involved), but shall not exceed 120 days total from the date of receipt of the Federal agency's written request consistent with paragraph (c)(1) of this section.

50 CFR 402.14**§ 402.14 Formal consultation.**

(a) Requirement for formal consultation. Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section. The Director may request a Federal agency to enter into consultation if he identifies any action of that agency that may affect listed species or critical habitat and for which there has been no consultation. When such a request is made, the Director shall forward to the Federal agency a written explanation of the basis for the request.

(b) Exceptions.

(1) A Federal agency need not initiate formal consultation if, as a result of the preparation of a biological assessment under § 402.12 or as a result of informal consultation with the Service under § 402.13, the Federal agency determines, with the written concurrence of the Director, that the proposed action is not likely to adversely affect any listed species or critical habitat.

(2) A Federal agency need not initiate formal consultation if a preliminary biological opinion, issued after early consultation under § 402.11, is confirmed as the final biological opinion.

(c) Initiation of formal consultation.

(1) A written request to initiate formal consultation shall be submitted to the Director and shall include:

(i) A description of the proposed action, including any measures intended to avoid, minimize, or offset effects of the action. Consistent with the nature and scope of the proposed action, the description shall provide sufficient detail to assess the effects of the action on listed species and critical habitat, including:

(A) The purpose of the action;

(B) The duration and timing of the action;

(C) The location of the action;

(D) The specific components of the action and how they will be carried out;

(E) Maps, drawings, blueprints, or similar schematics of the action; and

(F) Any other available information related to the nature and scope of the proposed action relevant to its effects on listed species or designated critical habitat.

(ii) A map or description of all areas to be affected directly or indirectly by the Federal action, and not merely the immediate area involved in the action (i.e., the action area as defined at § 402.02).

(iii) Information obtained by or in the possession of the Federal agency and any applicant on the listed species and designated critical habitat in the action area (as required by paragraph (c)(1)(ii) of this section), including available information such as the presence, abundance, density, or periodic occurrence of listed species and the condition and location of the species' habitat, including any critical habitat.

(iv) A description of the effects of the action and an analysis of any cumulative effects.

(v) A summary of any relevant information provided by the applicant, if available.

(vi) Any other relevant available information on the effects of the proposed action on listed species or designated critical habitat, including any relevant reports such as environmental impact statements and environmental assessments.

(2) A Federal agency may submit existing documents prepared for the proposed action such as NEPA analyses or other reports in substitution for the initiation package outlined in this paragraph (c). However, any such substitution shall be accompanied by a written summary specifying the location of the information that satisfies the elements above in the submitted document(s).

(3) Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with § 402.12.

(4) Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area, a programmatic consultation, or a segment of a comprehensive plan. The provision in this paragraph (c)(4) does not relieve the Federal agency of the requirements for considering the effects of the action or actions as a whole.

(d) Responsibility to provide best scientific and commercial data available. The Federal agency requesting formal consultation shall provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat. This information may include the results of studies or surveys conducted by the Federal agency or the designated non-Federal representative. The Federal agency shall provide any applicant with the opportunity to submit information for consideration during the consultation.

(e) Duration and extension of formal consultation. Formal consultation concludes within 90 days after its initiation unless extended as provided below. If an applicant is not involved, the Service and the Federal agency may mutually agree to extend the consultation for a specific time period. If an applicant is involved, the Service and the Federal agency may mutually agree to extend the consultation provided

that the Service submits to the applicant, before the close of the 90 days, a written statement setting forth:

- (1) The reasons why a longer period is required,
- (2) The information that is required to complete the consultation, and
- (3) The estimated date on which the consultation will be completed.

A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. Within 45 days after concluding formal consultation, the Service shall deliver a biological opinion to the Federal agency and any applicant.

(f) Additional data. When the Service determines that additional data would provide a better information base from which to formulate a biological opinion, the Director may request an extension of formal consultation and request that the Federal agency obtain additional data to determine how or to what extent the action may affect listed species or critical habitat. If formal consultation is extended by mutual agreement according to § 402.14(e), the Federal agency shall obtain, to the extent practicable, that data which can be developed within the scope of the extension. The responsibility for conducting and funding any studies belongs to the Federal agency and the applicant, not the Service. The Service's request for additional data is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act.

If no extension of formal consultation is agreed to, the Director will issue a biological opinion using the best scientific and commercial data available.

(g) Service responsibilities. Service responsibilities during formal consultation are as follows:

- (1)** Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.
- (2)** Evaluate the current status and environmental baseline of the listed species or critical habitat.
- (3)** Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.
- (4)** Add the effects of the action and cumulative effects to the environmental baseline and in light of the status of the species and critical habitat, formulate the Service's opinion as to whether the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.
- (5)** Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1) through (3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section

7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45-day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45-day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10-day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take is reasonably certain to occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions as proposed or taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation. Measures included in the proposed action or a reasonable and prudent alternative that are intended to avoid, minimize, or offset the effects of an action are considered like other portions of the action and do not require any additional demonstration of binding plans.

(h) Biological opinions.

(1) The biological opinion shall include:

- (i)** A summary of the information on which the opinion is based;
- (ii)** A detailed discussion of the environmental baseline of the listed species and critical habitat;
- (iii)** A detailed discussion of the effects of the action on listed species or critical habitat; and
- (iv)** The Service's opinion on whether the action is:
 - (A)** Likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion); or

(B) Not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a “no jeopardy” biological opinion).

(2) A “jeopardy” biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, the Service will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(3) The Service may adopt all or part of:

(i) A Federal agency’s initiation package; or

(ii) The Service’s analysis required to issue a permit under section 10(a) of the Act in its biological opinion.

(4) A Federal agency and the Service may agree to follow an optional collaborative process that would further the ability of the Service to adopt the information and analysis provided by the Federal agency during consultation in the development of the Service’s biological opinion to improve efficiency in the consultation process and reduce duplicative efforts. The Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat, and other relevant factors to determine whether an action or a class of actions is appropriate for this process. The Federal agency and the Service may develop coordination procedures that would facilitate adoption of the

initiation package with any necessary supplementary analyses and incidental take statement to be added by the Service, if appropriate, as the Service's biological opinion in fulfillment of section 7(b) of the Act.

(i) Incidental take.

(1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), and, in the case of marine mammals, where the taking is authorized pursuant to section 101(a)(5) of the Marine Mammal Protection Act of 1972, the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact of incidental taking as the amount or extent of such taking. A surrogate (e.g., similarly affected species or habitat or ecological conditions) may be used to express the amount or extent of anticipated take, provided that the biological opinion or incidental take statement: Describes the causal link between the surrogate and take of the listed species, explains why it is not practical to express the amount or extent of anticipated take or to monitor take-related impacts in terms of individuals of the listed species, and sets a clear standard for determining when the level of anticipated take has been exceeded;

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact of incidental taking on the species;

(iii) In the case of marine mammals, specifies those measures that are necessary to comply with section 101(a)(5) of the Marine Mammal Protection Act of 1972 and applicable regulations with regard to such taking;

(iv) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or any applicant to implement the measures specified under paragraphs (i)(1)(ii) and (iii) of this section; and

(v) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action, may involve only minor changes, and may include measures implemented inside or outside of the action area that avoid, reduce, or offset the impact of incidental take.

(3) Priority should be given to developing reasonable and prudent measures and terms and conditions that avoid or reduce the amount or extent of incidental taking anticipated to occur within the action area. To the extent it

is anticipated that the action will cause incidental take that cannot feasibly be avoided or reduced in the action area, the Services may set forth additional reasonable and prudent measures and terms and conditions that serve to minimize the impact of such taking on the species inside or outside the action area.

(4) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45 and 18.27 for FWS and 50 CFR 216.105 and 222.301(h) for NMFS.

(5) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this section, is exceeded, the Federal agency must reinitiate consultation immediately.

(6) Any taking that is subject to a statement as specified in paragraph (i)(1) of this section and that is in compliance with the terms and conditions of that statement is not a prohibited taking under the Act, and no other authorization or permit under the Act is required.

(7) For a framework programmatic action, an incidental take statement is not required at the programmatic level; any incidental take resulting from any action subsequently authorized, funded, or carried out under the program will be addressed in subsequent section 7 consultation, as appropriate. For a mixed programmatic action, an incidental take statement is required at the

programmatic level only for those program actions that are reasonably certain to cause take and are not subject to further section 7 consultation.

(j) Conservation recommendations. The Service may provide with the biological opinion a statement containing discretionary conservation recommendations. Conservation recommendations are advisory and are not intended to carry any binding legal force.

(k) Incremental steps. When the action is authorized by a statute that allows the agency to take incremental steps toward the completion of the action, the Service shall, if requested by the Federal agency, issue a biological opinion on the incremental step being considered, including its views on the entire action. Upon the issuance of such a biological opinion, the Federal agency may proceed with or authorize the incremental steps of the action if:

- (1)** The biological opinion does not conclude that the incremental step would violate section 7(a)(2);
- (2)** The Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step;
- (3)** The Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action;
- (4)** The incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and

(5) There is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

(I) Expedited consultations. Expedited consultation is an optional formal consultation process that a Federal agency and the Service may enter into upon mutual agreement. To determine whether an action or a class of actions is appropriate for this type of consultation, the Federal agency and the Service shall consider the nature, size, and scope of the action or its anticipated effects on listed species or critical habitat and other relevant factors. Conservation actions whose primary purpose is to have beneficial effects on listed species will likely be considered appropriate for expedited consultation.

(1) Expedited timelines. Upon agreement to use this expedited consultation process, the Federal agency and the Service shall establish the expedited timelines for the completion of this consultation process.

(2) Federal agency responsibilities. To request initiation of expedited consultation, the Federal agency shall provide all the information required to initiate consultation under paragraph (c) of this section. To maximize efficiency and ensure that it develops the appropriate level of information, the Federal agency is encouraged to develop its initiation package in coordination with the Service.

(3) Service responsibilities. In addition to the Service's responsibilities under the provisions of this section, the Service will:

(i) Provide relevant species information to the Federal agency and guidance to assist the Federal agency in completing its effects analysis in the initiation package; and

(ii) Conclude the consultation and issue a biological opinion within the agreed-upon timeframes.

(m) Termination of consultation.

(1) Formal consultation is terminated with the issuance of the biological opinion.

(2) If during any stage of consultation a Federal agency determines that its proposed action is not likely to occur, the consultation may be terminated by written notice to the Service.

(3) If during any stage of consultation a Federal agency determines, with the concurrence of the Director, that its proposed action is not likely to adversely affect any listed species or critical habitat, the consultation is terminated.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 402

**Interagency Cooperation—
Endangered Species Act of 1973, as
Amended; Final Rule**

AGENCIES: Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Final rule.

SUMMARY: This final rulemaking establishes the procedural regulations governing interagency cooperation under section 7 of the Endangered Species Act of 1973, as amended (the "Act"). The Act requires Federal agencies, in consultation with and with the assistance of the Secretaries of the Interior and Commerce, to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of the critical habitat of such species. The Endangered Species Act Amendments of 1978, 1979, and 1982 (the "Amendments") changed the consultation requirements of section 7. This final rulemaking amends the existing rules governing section 7 consultation by implementing the changes required by the Amendments and by incorporating other procedural changes designed to improve interagency cooperation.

EFFECTIVE DATE: July 3, 1986.

FOR FURTHER INFORMATION CONTACT: Marvin E. Moriarty, Acting Chief, Office of Endangered Species, U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240 (703-235-2771); or Charles Karnella, Protected Species Division, Office of Protected Species and Habitat Conservation, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Department of Commerce, Washington, D.C. 20235 (202-634-7461).

SUPPLEMENTARY INFORMATION:

Background

On January 4, 1978, the Department of the Interior, through the United States Fish and Wildlife Service (FWS), and the Department of Commerce, through the National Marine Fisheries Service (NMFS), established procedures for the

Act's consultation process by implementing the interagency cooperation requirements of section 7 (50 CFR Part 402, "1978 rule"). The consultation process is designed to assist Federal agencies in complying with the requirements of section 7 and provides such agencies with advice and guidance from the Secretary on whether an action complies with the substantive requirements of section 7.

The Secretaries of the Interior and Commerce (the "Secretary") share responsibilities for conducting consultations pursuant to section 7 of the Act. Generally, marine species are under the jurisdiction of the Secretary of Commerce and all other species are under the jurisdiction of the Secretary of the Interior. Authority to conduct consultations has been delegated by the Secretary of the Interior to the Director of the FWS and by the Secretary of Commerce to the Assistant Administrator for Fisheries, NMFS, National Oceanic and Atmospheric Administration.

Section 7(a)(1) of the Act authorizes Federal agencies, in consultation with and with the assistance of the Secretary of the Interior or Commerce, depending on the species involved, to utilize their resources in furtherance of the purposes of the Act by carrying out programs for the conservation of endangered species and threatened species ("listed species") listed pursuant to section 4 of the Act.

Section 7(a)(2) of the Act requires Federal agencies, in consultation with and with the assistance of the Secretary, to insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of habitat of such species which has been designated as critical ("critical habitat"). Although Federal agency authority and responsibility under section 7 have remained virtually intact from the 1973 Act, the Amendments made significant procedural changes in the section 7 consultation procedures.

The 1978 Amendments formalized the process for the issuance of the Secretary's opinion ("biological opinions"), and required that the opinion include "reasonable and prudent alternatives" in cases where the proposed Federal action, in the opinion of the Secretary, would jeopardize the continued existence of a listed species or result in the destruction or adverse modification of its critical habitat. The 1978 Amendments also added section 7(c), requiring the preparation of biological assessments in appropriate instances. section 7(d) of the Act, also

added by the 1978 Amendments, prohibits a Federal agency or any involved permit or license applicant, after initiation of consultation, from making an irreversible or irretrievable commitment of resources which would foreclose the adoption of any reasonable and prudent alternatives.

Perhaps the most significant part of the 1978 Amendments was the creation of the Endangered Species Committee, which is authorized to grant exemptions from the requirements of section 7(a)(2) in appropriate cases. Regulations governing the submission of exemption applications and consideration of such applications by the Endangered Species Committee are presently codified at 50 CFR Parts 450-453. Although this final rule on consultation procedures does not deal directly with exemptions, good faith adherence to the consultation requirements of section 7 is a statutory prerequisite for entry into the exemption process.

The 1979 Amendments slightly altered the Federal agency's substantive obligation under section 7(a)(2) from insuring that its action "does not jeopardize" listed species or adversely modify the critical habitat of such species to insuring that its action "is not likely to jeopardize" such species or critical habitat. Congress expressly provided that the consultation and resultant biological opinion be based upon the "best scientific and commercial data available." These changes made the consultation process more flexible and established a reasonable information standard to be followed by the NMFS and FWS (the "Service") and other Federal agencies. The 1979 Amendments added a requirement that all Federal agencies confer with the Secretary on all actions that are likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat.

The 1982 Amendments also established several new processes under section 7. First, a new subsection 7(b)(4) allows for the issuance of an "incidental take statement" along with a biological opinion. This "incidental take statement" operates to exempt the Federal agency and any permit or license applicant involved from the section 9 "taking" prohibitions under the Act if the subsequent implementation of the action is consistent with the terms and conditions of the incidental take statement.

Second, the 1982 Amendments provide an opportunity for permit or license applicant involvement in all

phases of the consultation procedures. A prospective permit or license applicant may request Federal agencies to initiate consultation in advance of filing for any needed license or permit, if they have reason to believe that their proposed actions may affect listed species or critical habitat. This new provision, under section 7(a)(3), for "early consultation" allows a prospective applicant the opportunity to discover, and attempt to resolve, potential endangered or threatened species conflicts early in the planning stage of the proposed action—a time at which alterations in project plans could involve much less expense and delay.

Further involvement of the applicant in the consultation procedures is provided by the requirement that the applicant be involved in time extensions. Congress amended section 7(c) to require the Federal agency to give written notice to the applicant explaining why any extension of the biological assessment deadline is needed. If formal consultation under section 7(a)(2) is extended by the Service and the Federal agency for up to 60 days, the Service must provide the applicant with a written explanation of the reasons for extension. Any extension past 60 days must be approved by the applicant. Clearly, the permit or license applicant plays an active role in the consultation process. The final rule recognizes this increased role of the applicant while retaining the requirement that formal communications flow between the Federal agency and the Service during the consultation process.

In order to implement these Amendments to section 7 and to otherwise improve the interagency cooperation process, the Service published a proposed rule on June 29, 1983 (48 FR 29990-30004). Although the Service originally specified a 60-day comment period for these revised section 7 regulations, the comment period was extended until September 30, 1983. The Service received approximately 70 comments from other Federal agencies, State governmental agencies, private organizations, and other individuals and entities on the proposed rule.

After careful consideration of these comments, the Service has modified the regulations to clarify the consultation process and to improve the overall organization of the regulations. These technical changes are more fully explained in the section-by-section analysis below and were made to accommodate concerns raised in the public comments.

General Comments

The majority of the comments received on the proposed rule focused on particular regulatory provisions or concepts. These specific comments are discussed in the section-by-section analysis. However, several commenters expressed general concerns with the proposed rule or addressed matters that went beyond the scope of the proposal.

These general comments ranged from praise for the comprehensiveness of the proposal to criticism for the proposal's alleged failure to require the level of analysis and protection mandated by the Act. The Service believes that this final rule properly and accurately implements the Amendments to the Act and affords the protection mandated by section 7.

The House of Representatives Committee on Merchant Marine and Fisheries ("House Committee"), which oversees the implementation of the Act, submitted comments on the proposed rule. The Committee commended the Service in its efforts to translate complex legislation into agency policy and noted specific areas that it believed did not conform to the legislative intent. These matters have been clarified in the final rule.

One commenter was concerned that the proposed rule confused the informal (nonmandatory) consultation components with the formal (required) components of the consultation process. To clarify this matter, the Service has distinguished optional procedures from required procedures in the final rule. For example, the conference procedures (§402.10) are required for Federal actions that are likely to jeopardize proposed species or proposed critical habitat and the formal consultation procedures (§402.14) are required for actions that may affect listed species or critical habitat. Additionally, biological assessments (§402.12) are required for "major construction activities." Early consultation (§402.11) and informal consultation (§402.13) are optional procedures and are clearly designated as such in the final rule.

Concerned about increased paperwork burdens and potential time commitments resulting from the proposal, one commenter complained that the proposed rule is burdensome, unnecessary, and unacceptable. The commenter noted that additional protection for listed species or their habitat would not result from these alleged increases in administrative burdens, and it urged that currently used processes be maintained. The Service emphasizes that the proposal was not intended to increase in any way the

paperwork burden of Federal agencies or any other participant in the consultation process. Moreover, the purpose of the proposal was to implement the Amendments to the Act in such a way as to streamline the consultation process while maintaining the protections afforded species under section 7. The concern of the commenter has been addressed to the extent possible by the Service's effort to clarify the consultation process in this final rule. Because section 7 imposes certain requirements on Federal agencies, any burdens recognized in this final rule are a creature of statutory law as implemented by these regulations.

Two commenters asserted that the Act protects habitat only when it is designated as the critical habitat of a listed species and, therefore, the Service must identify areas of critical habitat for all listed species to assure adequate protection. It is true that the Service has not designated critical habitat for all listed species. The Service has consistently taken the position that it is not prudent to designate critical habitat for a species if to do so would increase the risk that the species might be taken or would otherwise not benefit the species. See 50 CFR 424.12(a). However, the commenters ignore the fact that section 7 protections attach to both designated critical habitat and to each individual of a listed species within the jurisdiction of the United States or on the high seas. An action could jeopardize the continued existence of a listed species through the destruction or adverse modification of its habitat, regardless of whether that habitat has been designated as "critical habitat." Thus, the failure of the Service to designate critical habitat for a given species does not automatically mean that its habitat is without protection.

Two States commented that Federal agencies charged with implementing the Act should recognize and cooperate with the States in resolving water resource issues within the context of section 7. Consistent with the Department's "good neighbor" policy, one commenter encouraged the Service to actively include affected States in any consultation process. The Service intends to cooperate with all State and local agencies to resolve water resource issues consistent with the requirements of the Act. The Service stands ready to receive any and all comments, data, or other input from any affected States that are interested in a particular section 7 consultation. However, consultation takes place between the Service, the Federal agency and, where applicable, a Federal permit or license applicant.

Several commenters stated that the proposal goes beyond the scope of the Act, thereby placing unjustifiable burdens on applicants and Federal agencies. They claimed that the rules would usurp Federal agency authority. One commenter questioned the ultimate authority of the Service to issue binding procedural regulations under section 7. In no way does the Service intend to use the consultation procedures of section 7 to establish substantive policy for Federal agencies. The Service performs strictly an advisory function under section 7 by consulting with other Federal agencies to identify and help resolve conflicts between listed species and their critical habitat and proposed actions. As part of its role, the Service issues biological opinions to assist the Federal agencies in conforming their proposed actions to the requirements of section 7. However, the Federal agency makes the ultimate decision as to whether its proposed action will satisfy the requirements of section 7(a)(2). The Service recognizes that the Federal agency has the primary responsibility for implementing section 7's substantive command, and the final rule does not usurp that function. The Service is satisfied that the final rule is within the scope of the authority provided in the Act.

Moreover, the Service is responsible for interpreting section 7 and for establishing a consultation process that is both uniform and consistent with statutory requirements. This issue was addressed in the preamble to the 1978 rule:

The FWS and NMFS are authorized under the Act to issue such regulations as they deem appropriate for the conservation of listed species. The two Services believe that these procedural regulations promote the conservation of listed species by implementing a uniform general framework as the starting point for consultation. Once the mandatory consultation has taken place, however, the ultimate responsibility for determining agency action in light of section 7 still rests with the particular Federal agency that was engaged in consultation. In this fashion, a standardized consultation process

is established which preserves ultimate agency administrative control over its activities or programs.

43 FR 870, 871 (Jan. 4, 1978). These procedural regulations do not dictate results but prescribe a process by which the Service will consult in keeping with the Act.

Several commenters stated that Congress did not intend that the Service interpret or implement section 7, and believed that the Service should recast the regulations as "nonbinding guidelines" that would govern only the Service's role in consultation. The Service notes that Congress reviewed with approval the section 7 regulations issued on January 4, 1978, when deliberating over the 1978 Amendments to the Act. See H.R. Conf. Rep. No. 1804, 95th Cong., 2d Sess. 18 (1978). Also, the Service was urged by the House Committee, through its comments on the proposed rule, to press forward with the issuance of this final rule. The Service is satisfied that it has ample authority and legislative mandate to issue this rule, and believes that uniform consultation standards and procedures are necessary to meet its obligations under section 7. However, the Service is aware that some Federal programs may require a modified consultation process, and therefore the Service has provided for the issuance of counterpart regulations under § 402.04.

Several general comments were received regarding programmatic adjustments and coordination. One commenter suggested that the Service maintain cumulative summaries of consultation activities in the Washington Office. The Service maintains copies of all biological opinions and monitors the issuance of biological opinions in an effort to ensure consistency and accuracy of findings. The Service submits that current review mechanisms are adequate and that, although the maintenance of cumulative consultation summaries might be useful, the increased costs are not justified.

Another commenter urged increased public participation in the consultation

process, including: (1) Public notice of each request for consultation; (2) public notice of the agenda for each consultation; (3) public notice of consultation results; (4) public comment periods; and, (5) prescribed rights to appeal by the public. Nothing in section 7 authorizes or requires the Service to provide for public involvement (other than that of the applicant) in the "interagency" consultation process. Moreover, due to the statutory time constraints imposed on the consultation procedures, it would not be practicable to implement such detailed public participation measures. Public participation may be provided within the Federal agency's decisionmaking process. However, that is a function of the agency's regulations or substantive legislation and not an issue to be raised in the context of consultation.

Finally, several questions were raised as to what rules will apply to pending consultations once the final rule becomes effective. The Service does not anticipate any dramatic change in procedure or additional burdens on Federal agencies because the statutory changes to section 7 have been in effect throughout the development of the final rule. When this rule becomes effective, all pending and future consultations must comply with the requirements of these regulations. The Service will cooperate with the Federal agencies and any applicants to ensure that there are no undue delays in ongoing consultations.

Section-by-Section Analysis

The following portion of the preamble explains the final rule, covering the substantive issues of each section, noteworthy modifications from the proposed rule, significant changes from the 1978 rule, and responses to public comments. To assist the reader, Table 1 presents a citation to each subsection of the proposed rule with appropriate cross-references to the location of that provision in the final rule and in the 1978 rule.

TABLE 1.—CROSS-REFERENCE OF SECTION 7 REGULATORY PROVISIONS: PROPOSAL—FINAL—1978 RULE

Proposal	Final	1978 Rule
§ 402.01(a)–(e)	§ 402.01(a)–(b)	§ 402.01
§ 402.02 Definitions	§ 402.02 Definitions	§ 402.02 Definitions
—(none)	—“Act”	(none)
—“Action”	—“Action”	—“Activities or programs”
—“Action area”	—“Action area”	(none)
—“Adversely affect”	(none)	(none)
—“Applicant”	—“Applicant”	(none)
—“Biological assessment”	—“Biological assessment” and “Major construction activity”	(none)
—“Biological opinion”	—“Biological opinion”	(none)
—“Conference”	—“Conference”	(none)
—“Conservation”	(none)	(none)
—“Conservation recommendations”	—“Conservation recommendations”	(none)
—“Consultation process”	(none)	(none)
—“Critical habitat”	—“Critical habitat”	—“Critical habitat”; § 402.05

TABLE 1.—CROSS-REFERENCE OF SECTION 7 REGULATORY PROVISIONS: PROPOSAL—FINAL—1978 RULE—Continued

Proposal	Final	1978 Rule
—“Cumulative effects”	—“Cumulative effects”	(none)
—“Designated non-Federal representative”	—“Designated non-Federal representative”; § 402.08	(none)
—“Destruction or adverse modification”	—“Destruction or adverse modification”	—“Destruction or adverse modification”
—“Director”	—“Director”	—“Director or Regional Director”
—“Early consultation”	—“Early consultation”	(none)
—“Effects of the action”	—“Effects of the action”	(none)
—“Federal agency”	(none)	—“Federal agency”
—“Formal consultation”	—“Formal consultation”	(none)
—“Further discussion”	(none)	(none)
—“Incidental take”	—“Incidental take”	(none)
—“Informal consultation”	—“Informal consultation”	(none)
—“Jeopardize the continued existence of”	—“Jeopardize the continued existence of”	—“Jeopardize the continued existence of”
—“Listed species”	—“Listed species”	—“Listed species”
—“Preliminary biological opinion”	—“Preliminary biological opinion”	(none)
—“Proposed critical habitat”	—“Proposed critical habitat”	(none)
—“Proposed species”	—“Proposed species”	(none)
—“Reasonable and prudent alternatives”	—“Reasonable and prudent alternatives”	(none)
(none)	—“Reasonable and prudent measures”	(none)
—“Recovery”	—“Recovery”	—“Recovery”
—“Service”	—“Service”	(none)
§ 402.03	§ 402.03	§ 402.03
§ 402.04	§ 402.04	§ 402.04(i)
§ 402.05	§ 402.05(a)–(b)	(none)
§ 402.10(a)	§ 402.06(a)	§ 402.04(b)(1)
—(b)	§ 402.06(a)	(none)
—(c)	(none)	(none)
—(d)	§ 402.07	§ 402.04(b)(2)
§ 402.11	§ 402.09	§ 402.04(a)(3)
§ 402.12(a)	§ 402.13(a)–(b)	§ 402.04(a)
—(b)	§ 402.12(a)–(k)	§ 402.04(c), (d)
§ 402.13(a)–(c)	§ 402.10(a)–(e)	(none)
§ 402.14	§ 402.11	(none)
§ 402.15(a)	§ 402.14(a)	§ 402.04(a)
—(b)	§ 402.11(f), 402.14(b)(2)	(none)
—(c)	§ 402.13(a), 402.14(b)	§ 402.04(a)
—(d)	§ 402.14(c)–(d)	—(a), (c), (d)
—(e)	—(e)	—(e), (f)
—(f)	—(g)	—(e)
—(g)	—(h)	—(a)
—(h)	—(h)–(i)	—(e)
—(i)(1)	§ 402.13(a)	(none)
—(i)(2)–(4)	§ 402.14(f), 402.15(b)	(none)
—(j)(1)	—(f)	§ 402.04(f)
—(j)(2)	—(k)	(none)
—(k)	—(a)	§ 402.04(a)
§ 402.16	(none)	(none)
§ 402.17(a)	§ 402.15(a)	§ 402.04(g)
—(b)	§ 402.15(c)	(none)
—(c)	§ 402.06(b)	§ 402.04(g)
§ 402.18	§ 402.16	§ 402.04(h)
§ 402.19	§ 402.14(f)	(none)

Subpart A—General

Section 402.01 Scope.

This section describes the purpose and scope of these regulations. Section 402.01 of the proposed rule contained an introductory paragraph and five subsections that were largely repetitive of other sections of the rule. These repetitive passages have been deleted from the final rule, and minor editorial corrections have been made.

Several commenters noted that, although § 402.01 acknowledges the language of section 7(a)(1) of the Act, no guidance is provided to enable Federal agencies to meet their conservation responsibilities under the Act. Claiming that the rules are silent as to Federal agency management programs required for the recovery of listed species, one commenter advised the Service to add a statement in the rule that would insure that Federal agencies address recovery

as well as detrimental effects through consultation. According to another commenter, this statement may include a request that Federal agencies issue policies and procedures to implement their authority under section 7(a)(1).

The Service notes that it is beyond the scope of these regulations to address how other Federal agencies should implement and exercise their authority to carry out conservation programs for listed species under section 7(a)(1). However, the Service stands ready to assist any Federal agency in developing and carrying out conservation programs. The Service cautions that all Federal actions including “conservation programs” are subject to the consultation requirements of section 7(a)(2) if they “may affect” listed species or their critical habitats. If the Service agrees, through informal consultation, that the action is not likely to adversely affect the species, then formal

consultation is not required [see § 402.13(a)–(b)]. Each Federal agency has the responsibility to implement its authority under section 7(a)(1). Further, any conservation program must comply with applicable permit requirements to the extent that such actions involve the taking of listed species. “Take,” as defined in the Act, means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct.

The 1978 rule extended the scope of section 7 beyond the territorial limits of the United States to the high seas and foreign countries. The proposed rule cut back the scope of section 7 to the United States, its territorial sea, and the outer continental shelf, because of the apparent domestic orientation of the consultation and exemption processes resulting from the Amendments, and because of the potential for interference with the sovereignty of foreign nations.

Several commenters asserted that the rules should continue to have extraterritorial effect. The scope of these regulations has been enlarged to cover Federal actions on the high seas but has not been expanded to include foreign countries. The Service finds that, because it already has jurisdiction under section 9(a)(1)(C) of the Act to regulate the taking of a listed fish or wildlife species on the high seas by all persons subject to the jurisdiction of the United States, concomitant jurisdiction under section 7 is implicit from Congressional concern that compliance with a section 7 incidental take statement not result in a taking violation under section 9(a)(1)(C), as provided in section 7(o)(2).

Although consultations on Federal actions in foreign countries will not be conducted under this rule, the Service maintains its strong commitment to the preservation of species and habitat worldwide. The Service will continue to list species which are found outside of United States jurisdiction when they are determined to be endangered or threatened.

Furthermore, Congress, in the International Environment Protection Act of 1983, 22 U.S.C. 2151q, made a finding that "the extinction of animal and plant species is an irreparable loss with potentially serious environmental and economic consequences for developing and developed countries alike." Accordingly, it places the preservation of species "through limitations on the pollution of natural ecosystems, and through the protection of wildlife habitats" as an "important objective of the United States development assistance." In furtherance of this policy, an Interagency Task Force was established to develop a national strategy for the protection and conservation of biological diversity in developing countries. The task force did not specifically recommend that international assistance activities be subject to consultation requirements, but did cite section 7(a)(2) in recommending that Federal agencies "should continue to adopt policies withholding support for certain types of projects that degrade or destroy fragile or protected lands." Until enacted by Congress, however, the recommendations of the task force will not be implemented in these regulations for the reasons stated above.

One commenter urged the Service to change the standard for initiating a section 7(a)(4) conference from "likely to jeopardize" to "would adversely affect." The regulation tracks the statute, and the Service lacks the authority to make the requested change. The same commenter noted that the section 7(d)

sentence referred to a "would avoid jeopardizing" standard. (Emphasis theirs.) Again, the Service adopts the regulation as in keeping with the statutory standard.

Another commenter stated that biological opinions need only be required after formal consultation under section 7(a)(2) of the Act and that this should be clarified in the rule. The Service disagrees because the statute requires that a "written statement" containing the Secretary's opinion be issued after the conclusion of both early and formal consultation. The rule has been amended slightly to clarify this requirement.

The commenter also requested that the sentence in proposed § 402.01(d) dealing with section 7(d) be amended by adding "measures" after the phrase "reasonable and prudent alternative[s]" to bring the regulation in line with the statute. The Service declines to make this change because it would tend to confuse "reasonable and prudent alternatives" that are included in jeopardy biological opinions with "reasonable and prudent measures" that are included in an incidental take statement under section 7(b)(4) of the Act. The proposed language describing the section 7(d) prohibition accurately implements the Act and is adopted in this final rule.

Section 402.02 Definitions.

This section sets out definitions of terms that are used throughout these regulations. As noted in Table 1, many definitions have been added to those included in the 1978 rule. Only comments which specifically addressed the definitions used in these regulations are discussed in this section. These terms are further discussed as they pertain to the consultation procedures in the appropriate, subsequent sections.

A definition of "Act" has been added to the final rule. It refers to the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

The definition of "action" parallels the former definition of "activities or programs," a term that predated the Amendments. Several changes have been made in the definition of "action" to accommodate public comments: First, the definition is expanded to cover activities occurring on the high seas. (See § 402.01 segment of the Preamble.) Second, the phrase "actions that are intended to conserve listed species or their habitat" was restored from the 1978 rule because of the decision to require Service review of all Federal actions that may affect listed species or their critical habitat. (See § 402.14 segment of the Preamble.) The Service

declines to define further or to delete the reference to actions that "indirectly cause modifications to the land, water, or air" in this definition. The concept of indirect effects is adequately addressed in the discussion of "cumulative effects" and "effects of the action."

The definition of "action area" is adopted from the proposed rule. Several commenters criticized the vagueness or apparent expansiveness caused by the reference to indirect effects in this definition. The definitions of "cumulative effects" and "effects of the action" further clarify the scope of "indirect effects."

The Service is not able to define specific spatial and temporal limits for the concept of indirect effects that would satisfy every conceivable situation, and believes that sufficient understanding of the term exists so that confusion will not occur. "Action area" is not limited to the immediate area involved in a Federal action.

"Applicant," an abbreviated term including all permit or license applicants, was defined in the proposed rule because of the increased role of permit or license applicants in the consultation process. Although the Act defines "permit or license applicant" in section 3(12), the Act's definition is of limited use in the consultation context because it focuses on the exemption process under section 7. The definition in the proposed rule broadly defines "applicant" as "any person who requires formal approval or authorization from a Federal agency as a prerequisite to conduct the action." Thus, applicants would include those seeking permits, licenses, leases, letters of authorization, and any other form of authorization or approval issued by a Federal agency as a prerequisite for carrying out the action.

One commenter suggested that the definition of applicant be amended to allow prospective permit applicants to participate in section 7 consultations involving the promulgation of regulations governing permit issuance. The applicant (or prospective applicant) is involved in the consultation process as a result of a specific permit or license application. The applicant may provide input regarding its concerns in the Federal agency's rulemaking process through the Administrative Procedure Act, 5 U.S.C. 551 *et seq.* Further, a prospective applicant could request early consultation through the Federal agency under § 402.11 of this rule on its prospective application during the course of agency rulemaking, if it desires early notice of potential conflicts and if it meets the requirements of these

regulations. This would involve interaction with the Service, but it would be limited in scope to the prospective application for the permit at issue, not a general consultation on the pending rulemaking. In response to another comment, the Service takes the position that it will not expand "applicant" to include those seeking funding from Federal agencies, unless the request for funding is coupled with a requirement that the person obtain Federal approval or authorization as a prerequisite for carrying out the action for which funding is sought. Finally, one commenter asked that the scope of the definition be expanded to include corporations, Federal agencies, and all other legal entities. The Service believes that the use of the word "person" in the definition satisfies the commenter's concern because of the broad definition of that term in section 3(13) of the Act. To clarify this point, the Service added a reference to the Act's definition of "person" in the definition of "applicant" in the final rule.

The definition of "biological assessment" in the final rule, derived from §§ 402.02 and 402.12(b)(4)(ii) of the proposed rule, clarifies that the assessment must include an evaluation of potential impacts. One commenter criticized the "vagueness" of the definition of "biological assessment" in the proposed rule, stating that it was unclear as to how a Federal agency would determine which species or critical habitat may be in the action area and how the agency would evaluate potential effects. The Service believes that this definition is adequate and that the process-oriented format in § 402.12 of the regulations adequately explains the scope and procedure of the biological assessment requirement.

The proposed definition of "biological opinion" has been adopted in these final rules. A biological opinion is the document that states the Service's opinion as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. One commenter suggested a third possible conclusion for biological opinions: "insufficient information to issue an opinion." The commenter argued that such a conclusion would eliminate the risk that the Service takes when issuing an opinion based on arguably inadequate data. The Service declines to add this third option. The legislative history of the Act is clear in requiring the Service to make a decision on the issue of likely jeopardy at the conclusion of formal consultation. The

Service will not sidestep this obligation, but instead will conclude either "jeopardy" or "no jeopardy" based on the best available data.

The definition of "conference" has been adopted as proposed. One commenter suggested that the conference not include recommendations to minimize or avoid adverse effects since they are not required by section 7(a)(4) of the Act. The commenter believed that such recommendations might result in legal action if not adopted. The Service, however, believes it has the responsibility not only to identify impacts but also to identify measures that would reduce those impacts.

The definition of "conservation" contained in the proposed rule was derived from the Act's definition in section 3(3). One commenter, characterizing the Service's interpretation of "conservation" as opposing the purposes of the Act and potentially encouraging the "further decline" of listed species, urged the Service to adopt the strict language of the statutory definition. The Service's definition in the proposed rule in no way discouraged recovery. In fact, the proposed definition tracked the statute except for its interpretation of "the point at which the measures provided pursuant to this Act are no longer necessary" as being equivalent to "the point at which [the species] may be removed from the Lists" The basic goal of the Act is to recover listed species through conservation measures. Bringing a species to the point at which the Act's protective measures are no longer necessary is the same as bringing the species to the point at which delisting is appropriate. However, to avoid any misunderstanding, the Service has deleted the definition from the final rule and will rely solely on the definition contained in section 3(3) of the Act. The Service declines specifically to include habitat modification (improvement or restoration), "off-site mitigation," captive propagation, and species reintroduction in the list of conservation methods and procedures, as suggested by certain commenters. Such activities are already adequately provided for in the Act's definition.

The term "conservation recommendations" was introduced in the proposed rule and explains the Service's role in helping agencies meet their section 7(a)(1) responsibilities. Several commenters feared that the Service would employ conservation recommendations to require Federal agencies to reformulate their actions that had received "no jeopardy"

biological opinions. This is not the purpose of conservation recommendations. They are nonbinding suggestions that a Federal agency may elect to implement in its proposed action. These recommendations should be consistent with the general scope, magnitude, and duration of a Federal action that is not likely to jeopardize a listed species or destroy or adversely modify its critical habitat. The Service, in answering the concerns noted above, is satisfied that it has clarified its position and that the regulatory definition should not be deleted. The Service has chosen to retain this definition with limited, technical changes because it believes that the opportunity to provide conservation recommendations, including minor design modifications, may minimize possible adverse effects and may avoid future section 7 conflicts for subsequent Federal actions in the same action area.

One commenter confused "conservation recommendations" with "reasonable and prudent alternatives" and believed that recommendations to reduce adverse impacts would violate section 7(a)(2), absent the granting of an exemption. The obligation of Federal agencies under section 7(a)(2) is to insure that the actions they authorize, fund, or carry out are not likely to jeopardize listed species or destroy or adversely modify their critical habitat. A showing of "adverse effect" does not necessarily violate section 7(a)(2), because the jeopardy standard is the ultimate barrier through which Federal agencies may not pass in conducting their actions. "Reasonable and prudent alternatives" represent avenues of fulfilling the action without violating the jeopardy standard. "Conservation recommendations" involve voluntary measures that the Federal agency has the discretion to undertake to avoid or reduce adverse effects of a proposed action that otherwise complies with the provisions of section 7(a)(2).

The definition of "consultation process" has been deleted from the final rule because it tended to confuse the statutory requirements and optional processes and because it added little to the public's understanding of the process. The definition in the proposed rule could have led persons to believe that early consultation and informal consultation are required, sequential steps of the overall consultation process. As discussed above, the only required components of the consultation process are a "conference" for proposed species, a "formal consultation" for listed species, and a biological assessment for "major construction activities."

The "critical habitat" definition contained in the proposed rule only referred to those sections of 50 CFR Parts 17 and 226 that contain the lists of those areas so designated. The mechanics of the designation process are more properly considered under the section 4 regulations (50 CFR Part 424). For purposes of determining whether any of their actions is likely to destroy or adversely modify critical habitat, Federal agencies involved in section 7 consultations need only be aware of those areas that have been designated by the Service as critical habitat. Two commenters requested that a definition of critical habitat be included in the final rule. The Service notes that the requested definition is contained in the Act and need not be repeated here.

"Cumulative effects" and "effects of the action" are defined in §402.02 of the final regulations. Under §402.14(g) (3) and (4) of the final rule, the Service will consider both the "effects of the action" subject to consultation and "cumulative effects" of other activities in determining whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat.

In determining the "effects of the action," the Director first will evaluate the status of the species or critical habitat at issue. This will involve consideration of the present environment in which the species or critical habitat exists, as well as the environment that will exist when the action is completed, in terms of the totality of factors affecting the species or critical habitat. The evaluation will serve as the baseline for determining the effects of the action on the species or critical habitat. The specific factors that form the environmental baseline are given in the definition of "effects of the action," as requested by some commenters.

"Effects of the action" include the direct and indirect effects of the action that is subject to consultation.

"Indirect effects" are those that are caused by the action and are later in time but are still reasonably certain to occur. They include the effects on listed species or critical habitat of future activities that are induced by the action subject to consultation and that occur after that action is completed. In *National Wildlife Federation v. Coleman*, 529 F.2d 359 (5th Cir. 1976), the Court of Appeals for the Fifth Circuit found that "indirect effects" which can be expected to result must be considered under section 7 of the Act. In that case, the court enjoined completion of a highway because the Department of

Transportation failed to consider the effects to the endangered sandhill crane from future private development that would result from construction of the highway. The Service will consider the effects to listed species from such future activities that are reasonably certain to occur under the analysis of "indirect effects." The Service's approach will be consistent with *National Wildlife Federation v. Coleman*, and the Service declines to narrow the scope of its review (as requested by one commenter) in light of existing case law.

Effects of the action also include direct and indirect effects of actions that are interrelated or interdependent with the proposal under consideration. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification; interdependent actions are those that have no significant independent utility apart from the action that is under consideration. As noted by one commenter, the "but for" test should be used to assess whether an activity is interrelated with or interdependent to the proposed action.

One commenter urged the Service to exclude Federal actions that have completed consultation from the environmental baseline unless it can be shown that the actions are reasonably certain to occur. The Service declines to adopt this suggestion. In issuing its biological opinion on an action, the Service's finding under section 7(a)(2) entails an assessment of the degree of impact that action will have on a listed species. Once evaluated, that degree of impact is factored into all future section 7 consultations conducted in the area. These impacts will continue to be considered as part of the environmental baseline unless the Service receives notice from the Federal agency that the proposed action will not be implemented or unless the biological opinion on the proposed action is no longer valid because reinitiation of consultation is required.

In response to one comment, the Service notes that Federal actions that have proceeded through early consultation and that have received "no jeopardy" preliminary biological opinions should be factored into the environmental baseline. These actions, to be eligible for early consultation, had to be nonspeculative, feasible actions, and, because the preliminary biological opinion can later be confirmed as a final biological opinion, this initial review and conclusion by the Service must be considered in other section 7 consultations.

The term "cumulative effects" means those effects on the species caused by

other projects and activities unrelated to the action under consultation that the Service will consider in formulating its biological opinion on the subject action. One commenter opposed the proposed definition of cumulative effects by arguing that the Act does not require an analysis of cumulative effects in a section 7 consultation. Citing section 7(c), the commenter noted that biological assessments may be limited to an examination of effects of "such action" on listed species. The commenter urged the Service to strike cumulative effects analysis from this rule because few Federal agencies have the capability to recognize or assess cumulative effects of State or private actions contemporaneously with conducting section 7 consultation. According to the commenter, the Service, as the expert on current status of listed species, should keep watch on these State and private activities that come on line in a particular action area. The Service responds that a Federal agency, when evaluating the environmental impacts of a proposed action, must comply with NEPA. Since this compliance includes an analysis of cumulative effects, the Service believes that it is the Federal agency's responsibility to develop this information. The cumulative effects analysis conducted in compliance with the broad definition under NEPA may be submitted to the Service by the Federal agency when initiating formal consultation. The Service can use this analysis and apply its narrower definition of cumulative effects when analyzing whether a proposed action, along with cumulative effects, violates section 7(a)(2) of the Act.

Other commenters, while not opposing the applicability of cumulative effects analysis to section 7 consultations, believed that the proposed scope of "cumulative effects" and "effects of the action" were too narrow. These commenters generally suggested that cumulative effects should include the effects of all reasonably foreseeable future Federal, State, and private actions. They stated that this scope would be more in line with that mandated under NEPA and argued that any lesser review could detrimentally affect endangered species. The commenters adamantly opposed any limitation on the foresight employed by the Service or Federal agencies that they believed would result from the proposal's construction of cumulative effects.

Section 7 consultation will analyze whether the "effects of the action" on listed species, plus any additional,

cumulative effects of State and private actions which are reasonably certain to occur in the action area, are likely to jeopardize the continued existence of that species. Based on this analysis, the Federal agency determines whether it can proceed without exceeding the jeopardy standard. If the jeopardy standard is exceeded, the proposed Federal action cannot proceed without an exemption. This is a substantive prohibition that applies to the Federal action involved in the consultation. In contrast, NEPA is procedural in nature, rather than substantive, which would warrant a more expanded review of cumulative effects. Otherwise, in a particular situation, the jeopardy prohibition could operate to block "nonjeopardy" actions because future, speculative effects occurring after the Federal action is over might, on a cumulative basis, jeopardize a listed species. Congress did not intend that Federal actions be precluded by such speculative actions.

Future Federal actions proposed for the same area would have to be separately evaluated under section 7 and could not occur unless they were able, in their own right, to avoid jeopardizing the continued existence of the affected species or destroying or adversely modifying critical habitat. Since all future Federal actions will at some point be subject to the section 7 consultation process pursuant to these regulations, their effects on a particular species will be considered at that time and will not be included in the cumulative effects analysis. However, those future State or private actions (*i.e.*, no Federal agency involvement) that are "reasonably certain to occur" must be factored into section 7(a)(2) evaluations. The Service agrees that cumulative effects that are reasonably certain to occur will be considered in determining the likelihood of jeopardy. The final rule is amended accordingly, to clarify the duty to consider cumulative effects.

One commenter thought that the "reasonably certain to occur" standard was far too narrow and that it should be amended to cover actions where proposals have been made, and implementation schedules have been established. This suggestion would open the door for speculative actions to be factored into the "cumulative effects" analysis, adding needless complexity into the consultation process and threatening potential Federal actions which pose minimal adverse impacts of their own with possible "jeopardy" opinions due to speculative, State or private projects that may never be implemented. For State and private

actions to be considered in the cumulative effects analysis, there must exist more than a mere possibility that the action may proceed. On the other hand, "reasonably certain to occur" does not mean that there is a guarantee that an action will occur. The Federal agency and the Service will consider the cumulative effects of those actions that are likely to occur, bearing in mind the economic, administrative, or legal hurdles which remain to be cleared. The Service declines to alter its "cumulative effects" definition to include State or private actions that are not likely to occur.

One issue was raised concerning the application of cumulative effects analysis to water projects. A commenter contended that State and private projects that possess senior water rights under State water law and that can "reasonably be expected to occur" concurrently with the Federal action should be considered as cumulative effects. The Service notes that any State or private project (*i.e.*, no Federal agency involvement) that is reasonably certain to occur must be considered during the analysis of cumulative effects. Further, the Service believes that Federal actions, whether authorized, funded, or carried out by Federal agencies, that possess senior water rights should be considered while analyzing the effects of the action. In order to determine the effects of the action when a water project is the subject of consultation in a State which follows the prior appropriation doctrine, the project's operation plan should indicate the priority of the project's water rights under State law and account for the future effects of senior conditional water rights.

On a related matter, the Associate Solicitor's opinion on the scope of cumulative effects cited in the proposed rule provided, in part, that only those effects of other projects that are reasonably certain to occur *prior* to the completion of the Federal action subject to consultation under section 7(a)(2) should be considered during formal consultation. This statement has been interpreted by some to exclude from cumulative effects analysis those future State and private actions that, while "reasonably certain to occur," would not be completed *before* the completion of the Federal action subject to consultation. Such an interpretation places undue emphasis on the use of the word "prior" while ignoring the central concept that the Associate Solicitor's opinion intended to project: that a proposed State or private activity be "reasonably certain to occur" in order to

be taken into account during cumulative impact analyses. If such a State or private project satisfies the "reasonable certainty" test, then it should be considered in the cumulative impact analysis, even if it would go on line sometime after completion of the federally authorized, funded, or carried out project which was the subject of consultation. To the extent that the Associate Solicitor's opinion created the opposite impression, the Service takes this opportunity to clarify this point.

Moreover, as suggested by some commenters, and for the reasons outlined above, the Service has deleted its reference to the Interior Department position on "cumulative effects" in 88 I.D. 903 (1981) in the definition section. The Service disagrees with the commenter who stated that the citation to the legal opinion in the proposed definition denied the public meaningful comment on these regulations. The policy was widely known, and it was explained in the preamble to the proposed rule. The Associate Solicitor's opinion on "cumulative effects" is published in Interior Decisions, a publication available to the general public. Finally, the opinion does not represent a policy change subject to Administrative Procedure Act (APA) informal rulemaking proceedings. It represented Interior's legal interpretation of the scope of "cumulative effects" under section 7, adopted and published in 1981 in keeping with APA requirements, 5 U.S.C. 552(a). Therefore, no rep proposal is needed on this issue.

The definition of "designated non-Federal representative" is adopted from the proposal in part. First, in response to a comment, the Service explains that the non-Federal representative may conduct informal consultations (§402.13) and/or prepare biological assessments (§402.12). However, Federal agencies cannot delegate their role in initiating formal consultation, a conference, or early consultation. The second sentence of the proposed definition has been deleted, but a new §402.08 has been added to further explain the role of the designated non-Federal representative.

The proposed definitions of "destruction or adverse modification" and "jeopardize the continued existence of" received a lot of attention from commenters. Both definitions contained, as did the 1978 rule, the phrase "survival and recovery." The final rule retains the language of the proposed definitions, except for the changes noted below. Also connected with these terms is the definition of "recovery." The "recovery" of a listed species means that the status

of the species has improved to the point at which it may be removed from the Lists of Endangered and Threatened Wildlife and Plants.

The principal controversy involving the "jeopardy" and "destruction or adverse modification" definitions was that, under the proposed rule, to find that an action is likely to jeopardize a listed species or result in the destruction or adverse modification of critical habitat, the Service must identify detrimental impacts to "both the survival and recovery" of the listed species. The conjunction "and" was used in the 1978 rule's definitions of these phrases, but the word "both" was added by the proposed rule to emphasize that, except in exceptional circumstances, injury to recovery alone would not warrant the issuance of a "jeopardy" biological opinion. The Service adopts these definitions substantially without change from the proposed rule; this does not represent a change in policy, as one commenter charged, because the Service has internally interpreted the "jeopardy" standard as requiring detrimental impacts to the continued existence of a species under a joint survival and recovery concept. Other Federal agencies are assured that the same "jeopardy" standard under which their actions have been evaluated in the past will be continued under this final rule.

Several commenters urged the Service to strike the "and" and insert "or" in the definitions of "jeopardy" and "destruction or adverse modification." They argued that injury to recovery for an already depleted species would require the issuance of a jeopardy opinion. They also remarked that the Service's position disregarded the conservation requirements of the Act, failed to adequately protect critical habitat, operated to weaken or nullify recovery efforts, and otherwise violated the purposes and policies of the Act.

These commenters misconstrued the Service's role in conducting consultations under section 7(a)(2) of the Act. The purpose of consultation is to identify conflicts between proposed Federal actions and the "jeopardy" standard of section 7(a)(2). The "continued existence" of the species is the key to the jeopardy standard, placing an emphasis on injury to a species' "survival." However, significant impairment of recovery efforts or other adverse effects which rise to the level of "jeopardizing" the "continued existence" of a listed species can also be the basis for issuing a "jeopardy" opinion. The Service acknowledges that, in many cases, the extreme threats

faced by some listed species will make the difference between injury to "survival" and to "recovery" virtually zero.

One commenter disagreed that actions adversely affecting survival of a species will also always adversely affect its recovery. The commenter did not cite examples where an action that jeopardized "survival" of a species would not jeopardize its "recovery." The Service is not aware of any examples and believes that it would be very difficult to recover a species whose survival had been placed in jeopardy. The very concept of "jeopardy" is that a Federal agency should not authorize, fund, or carry out an action that would injure a listed species' chances for survival to the point that recovery is not attainable. If survival is jeopardized, recovery is also jeopardized. As noted above, though, these concepts are generally considered together in analyzing effects, and it is difficult to draw clear-cut distinctions.

The concept of "survival" is discussed above, but is not defined in the Act or in these regulations. Two commenters felt that "survival" should be defined in the regulations, and one urged the Service to adopt the following specific definition:

"Survival" for a species means retention of a sufficient number of individuals and/or populations with necessary habitat to insure that the species will keep its integrity in the face of genetic recombination and known environmental fluctuations.

The Service agrees with the criteria set out in the above definition, but declines to adopt a regulatory definition for "survival" because this concept varies widely among listed species. The Service will apply the statutory standard of jeopardy to the continued existence of a species on a case-by-case basis, taking into account the particular needs of and the severity and immediacy of threats posed to a listed species. The Service is not attempting to predetermine the results of any future consultations by announcing these interpretations of the "jeopardy" standard, but instead is emphasizing what "jeopardy" is and how it should be applied in the section 7(a)(2) process.

One commenter urged the Service to go further and forbid any Federal action to proceed, regardless of a "no jeopardy" finding, if the proposed action would adversely affect the recovery of a listed species. Numerous commenters cited sections 2(c)(1), 3(3), and 7(a)(1) of the Act as authority for the Service to ban Federal agency actions that "violate the requirement to conserve endangered species."

The commenters misinterpret the statutory changes which the Amendments have made to section 7, and they misconstrue court decisions which have noted the apparent "heightened" responsibility of the Secretary. The Service will undertake programs for the conservation of listed species and will consult with other Federal agencies attempting to do the same. The Service will not, nor does it have the authority to, mandate how or when other Federal agencies are to implement their responsibilities under section 7(a)(1), nor is the Service authorized to issue a biological opinion under section 7(a)(1) of the Act. Section 7(a)(1) has a limited purpose under the Act: to authorize Federal agencies to factor endangered species conservation into their planning processes, regardless of other statutory directives.

In contrast, section 7(a)(2) contains the mandatory "jeopardy" standard. The prohibitory features of section 7, and the exemption process added by the 1978 Amendments, focus on the provisions of section 7(a)(2). Although there is no express legislative history directly weighing and comparing the relative strengths of section 7(a)(1) with 7(a)(2), there can be no doubt that Congress considered the jeopardy standard of section 7(a)(2) as being the substantive cornerstone of section 7:

The term "is likely to jeopardize" is used because the *fundamental* obligation of section 7(a) of the act is that Federal agencies insure their actions do not jeopardize the continued existence of an endangered or threatened species.

S. Rep. No. 151, 96th Cong., 1st Sess. 4 (1979) (emphasis added). Congress intended that the "jeopardy" standard be the ultimate barrier past which Federal actions may not proceed, absent the issuance of an exemption. The commenters' argument would require Federal actions to halt if they failed to conserve listed species, a result clearly not intended by Congress. Congress intended that actions that do not violate section 7(a)(2), or actions receiving an exemption from the requirements of that subsection, be allowed to proceed.

Commenters argued that it would be a violation of section 7(a)(1) for the Service to issue a "no jeopardy" biological opinion for a proposed Federal action that would have an adverse effect on the recovery of a listed species. As previously stated, the Service lacks authority to issue biological opinions under that subsection, and the Act does not mandate particular actions to be taken by Federal agencies to implement 7(a)(1). Furthermore, adverse effects not

rising to the level of "jeopardizing the continued existence" of a listed species cannot be the basis for issuing a jeopardy opinion.

The Service disputes two commenters' assertions that "the Service now proposes to allow the 'continued existence' of a listed species to reach a state of likely jeopardy." The Service has followed and will continue to follow the policy of strictly applying the jeopardy standard of section 7(a)(2) in the consultation process. The Service has not and will not relax the statutory standard.

One commenter stated that limiting the definition of "destruction or adverse modification" to critical habitat is illogical. This limitation is mandated by the strict language of section 7(a)(2) and cannot be altered by the Service, although habitat destruction can be the basis for a jeopardy opinion in appropriate cases.

Another commenter requested that examples be given of actions that might indirectly alter critical habitat. The Service responds with the following examples of indirect alteration of critical habitat (which is not intended as an exclusive list): ground water pumping that occurs on land adjacent to the critical habitat area, but nevertheless diminishes essential ground water levels within the critical habitat; air pollution created by an action not occurring directly on the critical habitat area that causes a deterioration of essential air quality levels in the critical habitat; contamination of water supply within the critical habitat caused by release of toxic substances outside of the critical habitat area; etc.

In the definition of "jeopardize the continued existence of," one commenter suggested the word "could" be substituted for "would" in the phrase "would be expected, directly or indirectly, to reduce appreciably the likelihood of . . . the survival and recovery of listed species . . ." Such a change would be an unwarranted deviation from the language of the 1978 rule in light of subsequent Amendments to the Act. The Service retains the substance of the proposed language, but does delete the phrase "or otherwise adversely affecting the species" because, as several commenters suggested, the phrase is confusing and adds nothing to the definition.

In response to several comments, the Service has modified the definition of "recovery" to make it clear that recovery is not attained until the threats to the species as analyzed under section 4(a)(1) of the Act have been removed. The protective measures provided for listed species under the Act are no

longer needed if endangered or threatened status is no longer applicable to a species under section 4(a)(1).

The definition of "Director" has been modified by the addition of the phrase "or his authorized representative" after "the FWS regional director" and "Assistant Administrator for Fisheries" to accommodate present and future delegations of authority to carry out certain consultation responsibilities. Although the Minerals Management Service requested that all Outer Continental Shelf (OCS) section 7 biological opinions issued by the FWS be signed by the Washington Office, the authority to sign such opinions will remain with the regional offices because they have been staffed specifically to conduct all interagency consultations and to sign the resulting biological opinions.

The term "early consultation" was included in the proposed rule pursuant to the provisions of section 7(a)(3). This section authorizes the Service to consult with Federal agencies at the request of prospective applicants, prior to the submission of the permit or license application to that Federal agency. The definition has been modified to reference the appropriate section of the Act.

One commenter requested that, instead of using the term "early consultation," the Service refer to this process as "consultation on behalf of prospective applicants." The commenter was concerned that, by calling this pre-application process "early consultation," the Service would fail to alert Federal agencies and applicants of the need to determine impacts to endangered or threatened species early in the planning stages of all of their actions, regardless of whether the consultation is early, informal, or formal. The Service retains the label "early consultation" due to its convenience, its frequent use in the committee reports on the 1982 Amendments, and its common acceptance within and outside the Service. The Service believes that the language provided in §402.14(a), advising Federal agencies to review their actions at the earliest possible time, provides adequate safeguards to address the commenters' concerns.

The definition of "Federal agency" has been deleted since it is defined in section 3(7) of the Act. The Service declines to expand the statutory definition to accommodate one commenter's concern. The statutory definition adequately provides notice that all departments, agencies, and instrumentalities of the United States come within the scope of section 7. The

Service will not interpret this term further in the final rule.

The definition of "formal consultation" has been modified to specify that it is the consultation required under section 7(a)(2) of the Act. Other minor, technical changes have also been made. The phrase "after it has been determined, through informal consultation with the Service, that its action may adversely affect listed species or critical habitat" has been deleted from the proposed definition because, as recommended by some commenters, informal consultation is strictly an optional process. Although the Federal agency may elect to enter into informal consultation to determine if formal consultation is required, the Federal agency can initiate formal consultation any time that it determines its action may affect listed species or critical habitat.

"Further discussion" was an optional process included in the proposed rule. It provided the Federal agency and any applicant the opportunity to continue consultation after the issuance of a biological opinion in order to discuss with the Service any reasonable and prudent alternatives and any conservation recommendations. Recommendations and alternatives could be refined or developed during these discussions, and consultation would terminate with the Federal agency's written notice of its final decision on the action. Because of concerns expressed by commenters, this provision contained in proposed §402.16 has been deleted from the final rule.

Although several commenters supported this provision, many opposed further discussion contending that it is unnecessary, that all reviews and discussions should occur prior to the issuance of the biological opinion, that it extends consultation beyond the statutory time limits, and that it lacks statutory authority. Although the process was optional, some commenters believed that there was an implication that the Federal agency or applicant would have a duty to engage in further discussion.

Although further discussion has been deleted, the Service is available to discuss the biological opinion, any reasonable and prudent alternatives, and any conservation recommendations with the Federal agency and any applicant on an informal basis. If revisions to the opinion are necessary, consultation can be reinitiated and a revised opinion issued.

"Incidental take" has been clarified in the final rule as those takes that result from, but are not the purpose of,

carrying out an otherwise lawful activity conducted by the Federal agency or the applicant. As requested by one commenter, the Service explains that otherwise lawful activities are those actions that meet all State and Federal legal requirements except for the prohibition against taking in section 9 of the Act. The Service believes that the definition, as clarified in the final rule, is adequate.

The definition of "informal consultation" has been clarified in the final rule to indicate that it is an optional process that includes all discussions, correspondence, etc., between the Service, Federal agency, and designated non-Federal representative prior to formal consultation. To address one commenter's concerns, "if required" has been included after "formal consultation" to clarify that formal consultation is not always required after informal consultation. Through informal consultation, a Federal agency may determine that formal consultation is not required.

The definition of "listed species" is adopted as proposed. Contrary to the concern of one commenter, aquatic invertebrates are not excluded from this definition, because all listed species in 50 CFR 17.11-17.12 are specifically included.

The definition of "major construction activity" was included in the definition of biological assessment in the proposed rule and is adopted substantially as proposed. As suggested by many commenters, it has been made a separate definition. Whether a Federal action is a major construction activity, as defined in these regulations, is the standard used for determining whether a Federal agency must prepare a biological assessment. A "major construction activity" is defined as a construction project (or other undertaking having similar physical impacts) that is a major Federal action significantly affecting the quality of the human environment for purposes of NEPA. The term encompasses dams, buildings, pipelines, roads, water resource developments, channel improvements, and other such undertakings which significantly modify the physical environment.

A vast array of comments were received concerning the scope of a major construction activity that requires the preparation of a biological assessment. Several commenters noted that only major Federal actions requiring the preparation of an environmental impact statement (EIS) pursuant to NEPA should require the preparation of a biological assessment

under section 7(c) of the Act. Other commenters argued that assessments can only be required for major Federal actions involving construction activities, and suggested that the phrase "or other undertakings having similar physical impacts" be eliminated from the definition. Four commenters thought that the standard in the proposed rule was too narrow, because the limitation to major Federal actions, and/or the limitation to construction projects and other undertakings having similar physical impacts, were arbitrary and without legal basis. The Service has adopted the definition of major construction activity as proposed for the reasons set out below.

The legislative history of section 7(c) of the Act plainly focused the mandatory duty to prepare biological assessments on "major Federal actions . . . designed primarily to result in the building or erection of dams, buildings, pipelines and the like." H.R. Conf. Rep. No. 697, *supra*. The two-pronged regulatory test adopted in this rule—major Federal action and construction project (or other undertaking having similar physical impacts)—clearly tracks the quoted language from the Conference Report to the 1979 Amendments. The Service will not require biological assessments for projects that are not major Federal actions for purposes of NEPA. Further, the Service will not require biological assessments for actions that do not involve construction or activities having physical impacts similar to construction, such as dredging, blasting, etc. This limitation derives support from the 1979 Conference Report reference to actions designed *primarily to result in* the building or erection of various projects. These other "potentially destructive activities," H.R. Rep. No. 1625, *supra*, having physical impacts similar to construction projects, will require the preparation of an assessment, but only if they are major Federal actions for purposes of NEPA.

The Service declines to limit the scope of the definition of a major construction activity to major Federal actions involving construction projects, because other potentially destructive activities that are major Federal actions may have similar physical impacts and should be included. The Service is confident that the courts will be able to apply this standard consistent with the Act and the legislative history.

Contrary to the belief of one commenter, the Service has not abrogated its authority under section 7(c). That commenter urged the Service to change this rule by requiring biological assessments "for actions that,

taking into consideration cumulative effects, may be 'potentially destructive.'" Citing a February 1980 legal opinion issued by the Assistant Solicitor for Fish and Wildlife, Department of the Interior, the commenter noted that cumulative effects may trigger the requirement that an assessment be prepared, although the Service must defer to the Federal agency's decision on whether a major Federal action exists. Contending that Congress would have used the word "shall" instead of "may" in the last sentence of section 7(c)(1) if it had intended that assessments be required only for major Federal actions for purposes of NEPA, the commenter argued that the definition of "major construction activity" should be expanded:

"Major Construction activity" means any planned, temporary, or permanent physical modification to the environment. Examples of such projects include but are not limited to, dredging, drilling, filling, mining, site preparation, road construction, the erection of structures such as dams and buildings, or any other potentially destructive activities.

The commenter's suggested language goes well beyond the above-cited legislative history of the Act which clearly limited the biological assessment requirement to major Federal actions within the meaning of NEPA that are construction projects or that involve similar physical impacts. Further, the legal opinion of the Assistant Solicitor cited by the commenter does not support the commenter's argument because that opinion dealt with cumulative effects of a proposed construction project and a basic rule of NEPA case law that cumulative impacts of an action can trigger the requirement that an EIS be prepared. Thus, the basic elements of this rule's requirements—major Federal action (e.g., EIS, or the functional equivalent, required) and construction project (or activity involving similar physical impacts)—were assumed to be appropriate standards by the Assistant Solicitor. The use of the word "may" instead of "shall" in section 7(c) means nothing more than Congressional intent that the duty to coordinate these review processes is discretionary with the Federal agency.

As requested by one commenter, the final definition clearly states that an action must be both a major Federal action for purposes of NEPA and a construction project (or other activity involving similar impacts). Therefore, it plainly follows that, although dams, pipelines, etc. are construction activities, a biological assessment is not

required unless the action is also a major Federal action.

Two commenters argued that OCS leasing, exploration, and development/production activities should be exempt from the section 7(c) requirement because such an analysis is presently covered by NEPA compliance as addressed in the Outer Continental Shelf Lands Act. Other commenters agreed with the Service that biological assessments would be required for development/production activities on the OCS, and, generally, would not be required for leasing and exploration activities that do not involve a significant modification of the physical environment. The Service adopts its position as proposed, because no exemption exists under section 7(c) if a biological assessment is required for an action. In some instances, OCS exploration activities may require the preparation of a biological assessment; e.g., major Federal action involving exploration through construction of artificial gravel islands. However, in most cases major Federal exploration activities on the OCS will involve the drilling of test wells, actions that will not require the preparation of assessments.

The definition of "preliminary biological opinion" is adopted as proposed.

The definition of "proposed critical habitat" is adopted as proposed with the addition of the phrase "or revised" after "designated." The commenter that suggested this correction accurately noted that proposals may be made to designate or revise critical habitat under section 4 of the Act.

The definition of "proposed species" is adopted as proposed.

"Reasonable and prudent alternatives" is defined in the final rule. Section 7(b) of the Act requires the Service to include reasonable and prudent alternatives, if any, in a "jeopardy" biological opinion. An alternative is considered reasonable and prudent only if it can be implemented by the Federal agency and any applicant in a manner consistent with the intended purpose of the action, and if the Director believes it would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat of such species. Further, the Service should be mindful of the limits of a Federal agency's jurisdiction and authority when prescribing a reasonable and prudent alternative. An alternative, to be reasonable and prudent, should be formulated in such a way that it can be implemented by a Federal agency consistent with the

scope of its legal authority and jurisdiction. However, the Service notes that a Federal agency's responsibility under section 7(a)(2) permeates the full range of discretionary authority held by that agency; i.e., the Service can specify a reasonable and prudent alternative that involves the maximum exercise of Federal agency authority when to do so is necessary, in the opinion of the Service, to avoid jeopardy. The Service recognizes that economic and technological feasibility are factors to be used in developing reasonable and prudent alternatives, as requested by one commenter. The definition of "reasonable and prudent alternatives" has been amended to reflect these considerations. If there are no alternatives that meet the definition of "reasonable and prudent alternatives," the Service will issue a "jeopardy" biological opinion without alternatives.

Two commenters stated that reasonable and prudent alternatives should include mitigation measures designed to reduce adverse effects, i.e., conservation recommendations. One of those commenters urged the Service to limit the scope of recommended alternatives to those "consistent with the scope, magnitude, and duration of the project as well as the extent of its adverse effects." First, because there is a distinction between "reasonable and prudent alternatives" (that satisfy section 7(a)(2)) and "conservation recommendations" (that are authorized by section 7(a)(1)), the Service declines to include conservation measures within the scope of the definition. Second, the Service agrees that reasonable and prudent alternatives should be consistent with the intended purpose of the action and should therefore be economically and technologically feasible, but the Service cannot limit its range of choices to the criteria suggested by the commenter. Reasonable and prudent alternatives must cover the full gamut of design changes that are economically and technologically feasible for an action, independent of who is sponsoring the action.

Two commenters asked that "reasonable and prudent measures" be defined, and the Service has inserted a definition in the final rule. This addition clarifies the distinction between "reasonable and prudent alternatives" included in a "jeopardy" biological opinion and "reasonable and prudent measures" provided in an incidental take statement. The Service agrees with several commenters that reasonable and prudent measures are not the same as reasonable and prudent alternatives. Substantial design and routing changes—appropriate only for

alternatives to avoid jeopardy—are inappropriate in the context of incidental take statements because the action already complies with section 7(a)(2). The commenter that advocated an "alternatives" approach for reasonable and prudent measures misapplied the legislative history of the 1982 Amendments. Reasonable and prudent measures were intended to minimize the level of incidental taking, but Congress also intended that the action go forward essentially as planned. Therefore, the Service believes that they should be minor changes that do not alter the basic design, location, duration, or timing of the action. The section 7 obligations of Federal agencies are not expanded by the application of reasonable and prudent measures, which strictly govern the scope of the section 9 exemption for incidental takings.

The definition of "Service" is adopted as proposed.

Section 402.03 Applicability.

This section, which explains the applicability of section 7, implicitly covers Federal activities within the territorial jurisdiction of the United States and upon the high seas as a result of the definition of "action" in § 402.02. The explanation for the scope of the term "action" is provided in the discussion under § 402.01 above.

Section 402.04 Counterpart Regulations.

The Service has retained the counterpart regulations section of the 1978 rule as the new § 402.04 that authorizes the drafting of joint counterpart regulations by Federal agencies and the Service. "These counterpart regulations would allow individual Federal agencies to 'fine tune' the general consultation framework to reflect their particular program responsibilities and obligations." 43 FR 870, 871 (Jan. 4, 1978).

Counterpart regulations must be published first as proposed rules with a minimum 60-day public comment period. Such counterpart regulations must retain the overall degree of protection afforded listed species required by the Act and these regulations. Changes in the general consultation process must be designed to enhance its efficiency without eliminating ultimate Federal agency responsibility for compliance with section 7. As long as the general consultation process is used as a starting point, Federal agencies can anticipate little difficulty in securing approval of the Service for counterpart regulations.

One Federal agency commented that the counterpart regulation process is a time-consuming alternative. The Service admits that informal rulemaking takes time and effort, but believes that the "fine tuning" that could occur through the development of counterpart regulations might, in the long run, provide a solid return in time and resources saved through the use of a more compatible consultation procedure.

Section 402.05 Emergencies.

Section 402.05 provides a modified consultation procedure for the Service to respond to emergency situations. This provision applies to situations involving acts of God, casualties, disasters, national defense or security emergencies (added to the rule in response to public comments), etc.

Upon request by the Federal agency, the Service may carry out consultation through procedures other than those provided under these regulations, as long as such emergency procedures are consistent with sections 7(a)-(d) of the Act. This allows, for example, consultation through informal means (e.g., a telephone call) and, therefore, rapid responses to emergency situations.

Several commenters suggested that specific procedures should be set out to provide guidance to Federal agencies facing emergency situations. One commenter suggested that consultation could be initiated informally, such as through a telephone call, and the Service could then communicate its information and recommendations over the telephone. Because of the severe time constraints inherent in an emergency, this informal approach is the method the Service anticipates will be used by a Federal agency to conduct a consultation for a *bona fide* emergency. One commenter felt that minimum requirements should include "documentation of the nature of the emergency and justification for an expedited consultation." The Service agrees and has required, in a new paragraph (b) to this section, that the nature of the emergency and the justification for using an expedited process be documented and forwarded to the Service. However, the Service has not required that this be done during the emergency or expedited consultation, as this may not always be possible. The new paragraph (b) requires that the Federal agency conduct an "after the fact" consultation. The Service will evaluate the information submitted by the Federal agency, *i.e.*, the nature of the emergency actions, justification for the expedited consultation, and an evaluation of the impacts to listed

species and critical habitat, and issue a biological opinion including the information and recommendations given during the emergency consultation. This will serve not only to document fully the consultation, but may assist the Federal agency in responding to similar emergencies.

One commenter argued that, when dealing with a fire, flood, earthquake, or storm, there is not enough time or opportunity for a Federal agency to undertake consultation through an alternate process determined by the Director to be consistent with section 7. The Service notes that the utmost flexibility is needed to handle the most extreme emergencies and believes that the informal process outlined in this section would satisfy the commenter's concern for the availability of prompt consultation and decisionmaking in emergency situations.

The Service further recognizes that it is sometimes necessary to take immediate steps to contain, limit, or alleviate an emergency in order to protect health, safety, and welfare prior to initiating any form of consultation. However, the Service would like to stress the fact that its early involvement is important in order to take advantage of its expertise in minimizing the effects of emergency response activities on endangered and threatened species. Federal agencies must exercise discretion when responding to an emergency as to when to consult with the Service. This will depend on the nature of the emergency and the actions that are immediately required. The Federal agency should contact the Service as soon as practicable, keeping in mind the informal nature of emergency consultation and Service expertise in minimizing the impacts of emergency response activities on endangered and threatened species.

Section 402.06 Coordination with Other Environmental Reviews.

This section on coordination with other environmental reviews contains paragraphs (a) and (b) of § 402.10 and paragraph (c) of § 402.17 of the proposed rule. The substance of these paragraphs has been adopted, but the format has been altered.

These regulations, following the 1978 rule, allow Federal agencies to coordinate their consultation, conference, and biological assessment responsibilities under the Act with the agency's responsibilities under other statutes such as NEPA (42 U.S.C. 4321 *et seq.*) or the Fish and Wildlife Coordination Act (FWCA, 16 U.S.C. 661 *et seq.*). The Service encourages Federal agencies to coordinate these

responsibilities, but believes it is preferable to allow Federal agencies to do so in a manner that best conforms to their particular actions and which they believe is most efficient. Therefore, the sentences in the proposed § 402.10(b) stating that biological assessments *should* be incorporated into the documents required by other statutes (such as NEPA) have been dropped from the final rule.

Several commenters applauded these paragraphs because the coordination of environmental reviews would reduce duplication of paperwork and save time. One commenter requested guidance on how a NEPA review of endangered species issues should be conducted. The Service is not in a position to provide criteria that will ensure adequate NEPA compliance on endangered species issues. The Service suggests that the commenter contact the Council on Environmental Quality, the agency in charge of NEPA compliance, to obtain such information.

Another commenter expressed concern that, in simplifying the consultation process, safeguards should be used to avoid potential abuse and substantive problems. The commenter feared that, without safeguards, NEPA compliance might be construed as being less necessary on endangered species matters. The Service is also concerned that it retain sufficient review capability to identify potential conflicts between proposed Federal actions and listed species. Therefore, it has slightly altered its consultation procedures in this final rule to ensure that all Federal actions that "may affect" listed species receive some degree of review under informal or formal consultation.

The concluding sentences of paragraph (a) emphasize that although, for example, a biological assessment can be incorporated into an EIS, the procedures of these regulations also must be satisfied to ensure adequate and timely analyses during the section 7 consultation process. These sentences also express the intent of the Service to avoid a fragmented analysis of environmental concerns through the Service's direct efforts to provide a coordinated review. The Service declines to delete these sentences as requested by several commenters.

Under paragraph (b), the Service agrees with a comment that the biological opinion should be stated in the final environmental impact statement or environmental assessment. A statement of the opinion may be a summary of its findings and conclusions, contrary to the fear of one commenter that the entire opinion must be repeated

in the text of the NEPA document. The Service does feel that the entire opinion should be attached as an exhibit to the NEPA document if completion time permits.

Section 402.07 Designation of Lead Agency.

This section, which governs the designation of a lead agency, is adopted from § 402.10(d) of the proposed rule. One commenter requested that the section be amended so that only the lead agency is required to notify the Director that it will be conducting consultation on behalf of itself and all other cooperating agencies. The Service has adopted this suggestion.

Section 402.08 Designation of Non-Federal Representative.

A new § 402.08 has been added to the final rule to clarify the role of the designated non-Federal representative and was derived from §§ 402.02 and 402.12 (a) and (b)(5) of the proposed rule. Because the designated non-Federal representative may or may not be the applicant, there is a difference in the role the representative can play in the consultation. If the representative is not the applicant, the information-gathering functions, through informal consultation (§ 402.13) and/or through the preparation of a biological assessment (§ 402.12), is the full extent of its participation. However, if the representative is an applicant, its role in consultation is two-fold. As the representative, it may conduct the information-gathering functions identified above; as the applicant, it may continue its participation into formal consultation.

If an applicant is involved and does not desire to be the designated non-Federal representative, the Federal agency and the applicant must agree on the party to be designated. The Director shall be notified, in writing, if a non-Federal entity has been designated to represent the Federal agency for the informal consultation or biological assessment procedures.

One commenter stated that prior notice to the Director of the designation of a non-Federal representative is unnecessary. The Service disagrees because there is a legitimate need for it to be certain of the Federal agency's concurrence in the representation. However, the Service notes that there is a degree of flexibility here; i.e., designation in advance for a continuous action or for a group of related actions is acceptable. In response to one comment, the Service agrees that the designated non-Federal representative may only submit a species list under the biological assessment procedures (§ 402.12) if the

Federal agency has, previously to or simultaneously with this notice, provided its written designation to the Director.

Another commenter questioned the Service's authority to conduct informal consultations with non-Federal representatives in place of the Federal agencies. The Service acknowledges that the Federal agency must retain the responsibility to initiate formal consultation along with its ultimate responsibility to ensure that its actions are not likely to jeopardize listed species, but the designation of a representative by the Federal agency to conduct informal consultation does not lessen these responsibilities or eliminate the Federal agency's duty to review its actions. Instead, the designation of a representative allows the Federal agency to coordinate all of its environmental reviews, thereby saving time and resources to obtain a single, comprehensive analysis of the action and its potential impacts. The agency must still review the work product and independently reach its own conclusions and decisions. The representative does the ground work (data compilation and synthesis); the Federal agency cannot delegate its duty to review, analyze, and formally consult.

Concerned that a conflict of interest could exist if applicants were allowed to be designated as non-Federal representatives, one commenter cited 40 CFR 1506.5(c) (NEPA regulation) as authority for eliminating applicants from the field of potential representatives. The Service declines to make the suggested change for the following reason. Section 7(c)(2) itself recognizes that exemption applicants (including permit or license applicants) may prepare biological assessments in cooperation with the Service and under the supervision of the Federal agency. This express statutory opportunity for "interested parties" (as applicants would always be) to prepare biological assessments runs counter to the NEPA rule and shows the clear Congressional intent in favor of full applicant involvement in the section 7 process. Although applicants may fill the role of non-Federal representatives, the ultimate responsibility for compliance with section 7 remains with the Federal agency. In response to one commenter, the regulations have been changed to eliminate the requirement that the Federal agency "participate in the preparation" of the biological assessment. The Service believes that the Federal agency may fulfill its responsibilities by providing guidance and supervision, and by independently reviewing and evaluating the work

product of the applicant. Responsibility for carrying out negotiations with the Service may not be delegated to the applicant/representative, as suggested by this commenter. In addition, Federal agencies cannot delegate their role in initiating formal consultation, conference, or early consultation.

Section 402.09 Irreversible and Irretrievable Commitment of Resources.

Section 7(d) of the Act provides that, after initiation of consultation required under section 7(a)(2), the Federal agency and any applicant shall make no irreversible or irretrievable commitment of resources with respect to the Federal action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternatives that would avoid violation of section 7(a)(2). This prohibition does not apply to actions affecting proposed species or proposed critical habitat. This mandatory restriction on commitment of resources is set out in § 402.09 of the final rule (formerly § 402.11 of the proposal). In response to comments, the language of the proposed rule was corrected to conform more closely to section 7(d). Another commenter requested that the sentence dealing with section 7(d) be amended by adding "measures" after the phrase "reasonable and prudent alternative[s]" to bring the regulation in line with the statute. The Service declines to make this change because it would tend to confuse "reasonable and prudent alternatives" that are included in jeopardy biological opinions with "reasonable and prudent measures" that are included in an incidental take statement under section 7(b)(4) of the Act. The proposed language describing the section 7(d) prohibition accurately implements the Act and is adopted in this final rule.

The proposed rule addressed the duration of the section 7(d) prohibition as follows:

This requirement exists until: a "no jeopardy" biological opinion is issued by the Service . . . ; the Federal agency adopts reasonable and prudent alternatives; or an exemption is granted under section 7(h).

Proposed rule, 48 FR 29990, 30000 (June 29, 1983), *proposed to be codified at* 50 CFR 402.11. Several commenters asked for a clarification or expansion of these criteria that terminate section 7(d) restrictions. Noting that the Act is silent as to when the section 7(d) prohibition ceases, one commenter contended that the prohibition should end when consultation is terminated. Another commenter, concerned that the proposed language would deprive Federal

agencies of the responsibility and authority to determine compliance with section 7(a)(2), urged the addition of a fourth criterion that would terminate the section 7(d) prohibition if "the Federal agency determines that its proposed action will not jeopardize the continued existence of endangered and threatened species or adversely affect critical habitat." Another commenter went further and urged the Service to adopt other criteria where Federal agency compliance with section 7(a)(2) would remove the section 7(d) restriction. Two other commenters felt that the second criterion—adoption of reasonable and prudent alternatives—must be restricted to those recommended by the Service. They opposed allowing the Federal agency to formulate its own "reasonable and prudent alternatives" without Service approval in order to avoid the prohibition of section 7(d).

The commenters raise valid concerns that illustrate the need to reexamine the duration of the prohibition against the irreversible and irretrievable commitment of resources. First, the Service recognizes that, although its biological opinions issued by authority of section 7(b) are entitled to great deference, the ultimate decision of whether to proceed with an action in light of section 7 responsibilities rests with the Federal agency. The proposed language did preempt Federal agency discretion by placing an agency that disagreed with the conclusion of the Service's biological opinion in the awkward position of facing section 7(d) restrictions on its action, even though it had determined through its own analysis that the section 7(a)(2) standards were satisfied. Second, case law indicates that section 7(d)'s proscriptive force continues while Federal agency efforts to conform its action to the requirements of section 7(a)(2) are "ongoing." See *North Slope Borough v. Andrus*, 642 F.2d 589, 611 n.143 (D.C. Cir. 1980); *Conservation Law Foundation of New England, Inc. v. Andrus*, 623 F.2d 712, 714 n.1 (1st Cir. 1979). The final rule has been amended to provide that the section 7(d) prohibition is in force during consultation and continues until the requirements of section 7(a)(2) are satisfied.

Therefore, if a Federal agency receives a "no jeopardy" biological opinion from the Service or chooses any reasonable and prudent alternative recommended by the Service, the requirements of section 7(a)(2) are met and the section 7(d) prohibition expires. If the Federal agency disagrees with a "jeopardy" biological opinion or chooses an alternative not provided by the

Service based on its own analysis, then the validity of the Federal agency's "no jeopardy" finding will decide whether section 7(a)(2) has been satisfied and whether section 7(d) no longer applies. If it is later determined that the finding is not valid, the Federal agency would be taking the risk of noncompliance with the Act.

Finally, one commenter asked that this section be amended to require Federal agencies to give written notice to the Service verifying that neither it nor any applicant involved has made any irreversible or irretrievable commitment of resources during consultation. The Act does not provide such authority, except arguably in the exemption process. A mandatory section 7(d) notice has not been adopted in this final rule regarding consultation procedures because section 7(d) is strictly prohibitory in nature and not consultative.

Subpart B—Consultation Procedures

There are five primary components within the section 7 consultation procedures—conference, early consultation, biological assessment, informal consultation, and formal consultation. Of these, only conference, formal consultation, and biological assessments may be required. Although a Federal agency may elect to use several of these procedures, they do not represent a mandatory, sequential process. As requested by one commenter, the following is a brief abstract of each component of the consultation process.

If a Federal agency determines that its action is likely to jeopardize the continued existence of any *proposed* species or result in the destruction or adverse modification of *proposed* critical habitat, the Federal agency is required to "confer" with the Service under § 402.10. The purpose of a conference is to identify and resolve potential conflicts between an action and proposed species or critical habitat. The Service will make advisory recommendations on ways to minimize or avoid adverse effects. If the proposed species or proposed critical habitat is subsequently listed or designated, respectively, then the Federal agency must consider whether formal consultation under § 402.14 is required.

"Early consultation" is an optional process that may be requested through the Federal agency by a prospective applicant to determine whether its proposed action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. Early consultation occurs prior to a

formal application for a Federal permit or license. Such early consultation is conducted between the Service and the Federal agency in cooperation with the prospective applicant. At the request of the prospective applicant, early consultation is initiated by the Federal agency responsible for issuing the permit or license and is generally conducted and concluded in the manner prescribed for "formal consultation." If the action is a "major construction activity," the biological assessment requirement of § 402.12 must be satisfied before early consultation is initiated. After concluding early consultation, the Service will deliver its preliminary biological opinion to the Federal agency and the prospective applicant.

After formal application is made for the permit or license but before its issuance, the Federal agency should submit to the Service a written request that the preliminary biological opinion be confirmed as a final biological opinion under section 7(a)(2). If the Service determines that no significant changes have occurred in either the proposed action or the information available since early consultation, no new impacts are anticipated, and no new species have been listed or critical habitat designated since early consultation, it will confirm that the preliminary biological opinion remains accurate and shall be treated as a final biological opinion issued under section 7(b) of the Act. Consultation will terminate in accordance with § 402.14(f). However, if the Service is unable to confirm the preliminary biological opinion due to any of the reasons outlined in § 402.11, formal consultation on that action must be initiated under § 402.14.

"Biological assessment" requirements apply to all major construction activities as defined in these regulations. Even if not required, Federal agencies may voluntarily prepare a biological assessment to assist them in fulfilling their section 7 responsibilities. Also, any person who wishes to apply for an exemption may voluntarily prepare such an assessment in cooperation with the Service and under the supervision of the appropriate Federal agency.

A biological assessment contains information concerning listed or proposed species or designated or proposed critical habitat that may be present in the action area and an evaluation of any potential effects of the action on such species and habitat. A biological assessment should be used in determining whether formal consultation or a conference is required.

"Informal consultation" includes all the contacts (discussions, correspondence, etc.) between the Federal agency or its designated non-Federal representative and the Service that take place prior to the initiation of any necessary formal consultation. Informal consultation may be used by the Federal agency in determining whether formal consultation under §402.14 or a conference under §402.10 is required.

"Formal consultation" is required under section 7(a)(2) of the Act. A Federal agency must initiate formal consultation if it determines that its action "may affect" any listed species or its critical habitat unless it determines through informal consultation or biological assessment procedures, with the written concurrence of the Service, that its action "is not likely to adversely affect" such species or habitat. If the action is a "major construction activity," the biological assessment requirement must be satisfied before formal consultation may begin. Formal consultation is concluded within 90 days or extended in accordance with the provisions of §402.14. Within 45 days after concluding formal consultation, the Service will deliver its biological opinion stating whether or not the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. If formal consultation results in a "jeopardy" biological opinion, reasonable and prudent alternatives, if any, will be included in the opinion.

These procedures are discussed more fully below, together with the sections governing post-consultation responsibilities of Federal agencies and the factors that require reinitiation of formal consultation. Specific public comments are treated on a section-by-section basis.

Section 402.10 Conference on Proposed Species or Proposed Critical Habitat.

The 1979 Amendments added the requirement in section 7(a)(4) that Federal agencies confer with the Service on any Federal action that is likely to jeopardize the continued existence of any proposed species or result in the destruction or adverse modification of proposed critical habitat. The purpose of this requirement is to identify and resolve potential conflicts between an action and proposed species or proposed critical habitat at an early point in the decisionmaking process. Conferences will be conducted on an informal basis between the Federal agency and the Service. The Service will make recommendations, if any, to

minimize or avoid adverse effects of the action on proposed species or proposed critical habitat. These recommendations are advisory in nature, because the "jeopardy" prohibition of section 7(a)(2) does not apply until the species is listed or the critical habitat is designated. However, the Federal agency and any applicant should give serious consideration to implementing the recommendations since, if the species is later listed or critical habitat designated, the Federal agency must review its action, regardless of its stage of completion, to determine whether consultation is required. In certain instances the Federal agency and the Service may conduct the conference in such a thorough manner that it would satisfy the consultation requirements of section 7(a)(2) if the proposed listing or designation is subsequently completed.

The conference procedures are not repetitive of work performed in the preparation of a biological assessment, as suggested by three commenters. First, the conference requirement applies to all Federal actions, while the biological assessment requirement only applies to actions that are "major construction activities." Second, the conference requirement applies to proposed species and proposed critical habitat, whereas biological assessments are required only when listed species or critical habitat may be present in the action area (although proposed species or proposed critical habitat should be covered in the assessment if they also may be present in the action area). Thus, the conference process fills the need to alert Federal agencies of possible steps that the agency might take at an early stage to adjust their actions to avoid jeopardizing a proposed species. The Service strongly encourages the implementation of the recommendations so the action would not violate section 7(a)(2) if the species is listed or the critical habitat designated.

After reviewing a biological assessment or other available information, the Service may determine that a conference is required for the proposed species or proposed critical habitat. A sentence has been added to the new paragraph (b) of §402.10 [proposed §402.13(a)] to point out the Service's responsibility to request a Federal agency to confer after a review of available information. The last sentence of the proposed paragraph (a) has been deleted since the new §402.08 clearly defines the role of the designated non-Federal representative. The Service declines to take the position that it can "require" the initiation of a conference, because the Federal agency bears the

ultimate responsibility to assess the likelihood of jeopardy to proposed species by its actions. However, the Service will vigilantly review biological assessments and other available information and fulfill its duty to make Federal agencies aware of their responsibilities under the Act.

The Service emphasizes the need for Federal agencies to confer because such efforts may not only minimize or avoid injury to proposed species but might also prevent the halting of an action if the species is subsequently listed:

Obviously, Federal agencies irreversibly committing resources and foreclosing alternatives to an action that is likely to jeopardize a proposed species do so with the risk that the species will eventually be formally listed and the prohibitions of section 7 will become applicable. The conferees do not believe that any Federal agency or permittee should make any irreversible or irretrievable commitments of resources for the purpose or with the intent of foreclosing otherwise reasonable alternatives or in order to secure an exemption pursuant to section 7(h).

H.R. Conf. Rep. No. 697, 96th Cong., 1st Sess. 13 (1979).

There is no requirement that Federal agencies confer with the Service on species that are candidates for listing proposals. However, for the reasons identified by Congress in the Conference Report to the 1979 Amendments on proposed species, the Service encourages Federal agencies to confer informally on candidate species when deemed appropriate to avoid jeopardy and to avoid potential economic loss through project modification if the species is later listed.

Several specific changes were recommended for proposed paragraph (a) [paragraphs (a) and (b) in the final rule]. One commenter felt that the reference to "potential endangered species conflicts" was too restrictive. The Service agrees that the proposed rule might have been construed so as to exclude threatened species. Therefore, the sentence has been adjusted to refer to all potential conflicts.

One commenter urged the Service to change the standard for initiating a section 7(a)(4) conference from "likely to jeopardize" to "would adversely affect." The regulation tracks the statute. The Service lacks the authority to make the requested change.

Several commenters urged the Service to make provisions for applicant involvement in the conference process. The Service agrees, and has added language in paragraphs (a), (c), and (e) of §402.10 to ensure that applicants have an opportunity to participate in the

conference, and that they receive a copy of the conclusions documented by the Service.

Another commenter asked that time limits be established for the conference process. The Service declines to establish time limits for the conference requirement. The timing of the section 7(a)(4) process is, in part, dictated by the progress of the proposed rulemaking to list a species or to designate critical habitat. Regardless of any time limits that the Service could establish, the conference requirement expires and consultation is required if the listing or critical habitat designation becomes final. The Service finds no reason to impose rigid time frames for conferences.

Paragraph (c) defines the nature and content of the conference. Basically, a "conference" involves informal discussions on the identification and possible avoidance or minimization of potential adverse effects to proposed species or proposed critical habitat from a Federal action. The reference to "informal discussions" should not be confused with "informal consultation," which is a distinct, but optional, component of consultation.

The Service declines to modify paragraph (c) by changing "advisory" recommendations to "conservation" recommendations, as suggested. Such a change may confuse conference with formal consultation, the required procedure in which discretionary "conservation recommendations" may be given. The Service also declines to adopt suggested provisions that would (1) require advisory recommendations to be made in every conference, (2) force the Service to notify the Federal agency of the date on which a final decision will be made on a listing proposal, or (3) require the Service to initiate emergency rulemaking proceedings to list a species or designate critical habitat if the Federal action is likely to jeopardize the species. Although required, conference is an informal process that has no substantive force. To force every conference into a regimented structure would be counterproductive and contrary to the intent of the Act. When appropriate, the Service will make advisory recommendations on ways to avoid or minimize adverse effects to proposed species or proposed critical habitat. During the conference, the Service will apprise the Federal agency of the progress of the listing or critical habitat proposal and will attempt to notify the Federal agency when the listing or critical habitat proposal becomes final. Emergency rulemaking is provided for under section 4(b)(7) of the

Act and will be used if appropriate under the circumstances.

One commenter suggested that the conference involve all of the steps of formal consultation, but on an informal basis so that if the listing becomes final, the conclusions and recommendations derived from the conference could be adopted as a final biological opinion. In some cases, a thorough, well-prepared conference might elucidate sufficient conclusions and recommendations to serve as the biological opinion, upon the final listing of a species. While section 7(a)(4) does not require Federal agencies to follow the section 7(a)(2) process for proposed species or proposed critical habitat, or specifically provide for the conversion of conference "conclusions and recommendations" into a final biological opinion [in contrast to explicit authority under section 7(b)(3)(B) for the conversion of preliminary biological opinions into final biological opinions], such a procedure is available to the Federal agency and the Service in appropriate instances.

If the information necessary to conduct a formal consultation is available at the conference stage, and if a formal procedure is deemed appropriate by both the Federal agency and the Service, the conference may be conducted through a procedure equivalent to formal consultation; the results, or opinion, derived from a "formal" conference may be adopted as the biological opinion when the proposed listing or designation is completed. It should be noted that the conference conclusions and recommendations would only be adopted as the biological opinion in those instances where no new data are developed, including that developed during the rulemaking process on the proposed listing or designation of critical habitat, and no changes to the Federal action are made which would alter the content of that opinion. By providing procedures which allow for a more extensive conference that may later be adopted as the biological opinion, the Service does not intend to expand upon the requirements of section 7(a)(4). Rather, this procedure is an option available to the Federal agency and the Service to help avoid conflicts and expedite consultation if the proposed species or critical habitat is listed or designated. Therefore, a new paragraph (d) is added to this final rule to acknowledge the availability of a "formal" conference procedure.

Paragraph (e) of §402.10 discusses the documentation of the results of the conference. If the action involves only proposed species or proposed critical

habitat, a copy of the recommendations will be forwarded by the Service to the Federal agency and any applicant. If an action also involves formal consultation on listed species or critical habitat, the Service will provide the recommendations on proposed species or proposed critical habitat with the biological opinion. As requested by some commenters, the final rule has been clarified to state that the conclusions of a conference will be provided with the biological opinion rather than made an integral part of ("consolidated in") the opinion. The Service does not intend that the informal nature of the conference be changed or that any of the requirements of formal consultation under section 7 be imposed on Federal agencies with respect to proposed species or proposed critical habitats unless the Federal agency specifically requests a more formal procedure. Early initiation of these discussions increases the chances of resolution of potential conflicts.

Section 402.11 Early Consultation.

The 1982 Amendments added a provision to the consultation process [section 7(a)(3)] designed to identify and to minimize, early in the planning stage of an action, potential conflicts between the action and listed species. These early consultation provisions authorize the Service to consult with Federal agencies at the request of and in cooperation with prospective applicants regarding the impact of proposed actions on listed species or critical habitat. These provisions are incorporated into the final regulations in §402.11 (§402.14 of the proposed rule). The intent of this provision is to involve the Service and State and local planning and conservation entities in the planning stages of actions. The Service believes that early consultation will be helpful in establishing a mechanism for early resolution of potential conflicts. Congress did not intend that this provision be used to authorize consultation for speculative or remote actions but rather only on actions which are likely to occur. The regulations require prospective applicants to provide sufficient information describing the project, its location, the scope of activities associated with it, and the anticipated impacts to listed species to enable the Federal agency and the Service to conduct meaningful early consultations.

The opportunity for an early consultation should expedite the permitting and other regulatory processes associated with actions requiring Federal authorizations.

Contrary to the interpretation of one commenter, early consultation is not a required process, but rather is an optional step that a prospective applicant can take to factor in section 7 considerations during the initial planning stage. Although early consultation contains most of the features of formal consultation, the Service declines to adopt the suggestion to place the early consultation provisions within the formal consultation section as a "special case." Early consultation, unlike formal, is not required and occurs before any application for a permit or license is filed, whereas formal consultation is a post-application process when applicants are involved. These differences are significant and merit the separation of these distinct processes into separate sections. However, because of the extensive similarities in the procedures for early and formal consultation, the final rule has been substantially modified in format to reference appropriate paragraphs in §402.14 (formal consultation) to avoid repetition of these common features. Although this has greatly shortened the early consultation section, the requirements and procedures have not been altered substantively.

One commenter was confused over the parameters of early consultation and informal consultation (§402.13). Informal consultation is a post-application process, as is formal consultation; early consultation is a pre-application process. There is no overlap. Designated non-Federal representatives can carry out informal consultation, and they can also carry out the biological assessment process if an assessment is required during the early consultation. Although only Federal agencies conduct early consultation directly with the Service, non-Federal representatives may continue to play a role in the data-gathering function of consultation.

Several commenters believed that proposed §402.14 took away the prospective applicant's right to request early consultation and to make the initial determination of possible impacts to listed species or critical habitat. The proposed rule preserved the prospective applicant's right to request early consultation but provided the Federal agency with the responsibility for determining impacts to listed species or critical habitat. In response to comments, the final rule has been rearranged to clarify the primary role of the applicant in making the initial determination and request to the Federal agency. However, the applicant's rights under section 7(a)(3) of

the Act are not unqualified, and the ultimate burden is on the applicant to meet certain threshold criteria.

Paragraph (a) of §402.11 outlines the purpose of early consultation and is adopted substantially as proposed in §402.14(b) and the first sentence of §402.14(c). The legislative history is clear that the prospective applicant must be involved to the greatest extent practicable in every aspect of the early consultation process. H.R. Conf. Rep. No. 835, 97th Cong., 2d Sess. 26 (1982). One commenter expressed concern that it may not be possible to have the applicant involved in every meeting and telephone call between the Federal agency and the Service. Therefore, acknowledging the practical limitations on involving the applicant in all consultation contacts (but still recognizing the need for continuous communication with the applicant), the second sentence of paragraph (a) now reads that the prospective applicant should be involved "throughout" (instead of "in every aspect of") the consultation process.

Paragraph (b) of §402.11 sets out the threshold conditions that must be satisfied before early consultation can be initiated and is derived from proposed §402.14(c). As suggested by one commenter, the prospective applicant's request for early consultation should be made in writing to the Federal agency.

The "may adversely affect" threshold for initiating early consultation has been expanded to "may affect." This action was taken because the more restrictive standard unnecessarily limited access to this early review procedure, especially since at the early planning stage of an action the exact nature of a possible effect could be difficult to define.

Section 402.14(c) of the proposal established that the Federal agency ensure that the following conditions be met prior to initiation of early consultation:

- (1) there must be a definitive proposal outlining the action and its effect;
- (2) it must be shown that the action is technologically, administratively, and legally feasible;
- (3) it must be shown that the applicant possesses adequate economic resources to conduct the action; and
- (4) it must be shown that the applicant possesses some property interest in the proposed site on which the action will occur.

Numerous comments were received on these criteria. Three commenters urged the Service to strike all four conditions because of their unreasonableness and the Service's lack

of authority to impose them on applicants. Other commenters criticized conditions (2) and (3) due to their ambiguity. Contending that enforcement of these conditions would preclude early consultation in many cases, the commenters noted that the information needed to meet these conditions is not available at the time that early consultation is most useful. The commenters also attacked condition (4), regarding the need to show an ownership interest in land, because early consultation would normally occur prior to the selection of an exact location for the project. Two commenters stated that conditions (1) and (2) are adequate for screening serious actions. One commenter suggested that only two criteria be addressed in determining eligibility for early consultation: scope of the project, and possible effects on listed species.

The Service was given explicit authority in section 7(a)(3) of the Act to issue guidelines that would prevent speculative or undefined actions from triggering early consultation.

The Committee expects that the Secretary will exclude from such early consultation those actions which are remote or speculative in nature and to include only those actions which the applicant can demonstrate are likely to occur The Committee further expects that the guidelines will require the prospective applicant to provide sufficient information describing the project, its location, and the scope of activities associated with it to enable the Secretary to carry out a meaningful consultation.

H.R. Rep. No. 567, 97th Cong., 2d Sess. 25 (1982).

The final rule retains proposed condition (1) that requires the nature and effect of a prospective action to be defined. Without adequate information, early consultation would be meaningless. Proposed condition (2) has been modified in the final rule to require that the prospective applicant certify that it intends to implement its proposal, if authorized. This will prevent highly speculative actions from entering early consultation. The Service believes that these two conditions are reasonable and will allow Federal agencies and the Service to focus their attention on concrete, feasible actions through meaningful, early consultations.

Proposed conditions (3) and (4) described above have been deleted. The Service agrees that these conditions went beyond the normal pre-application information-gathering practices of Federal agencies and that they might have discouraged early consultations unnecessarily.

Paragraph (c) of § 402.11 is adopted from proposed § 402.14(a) and the introductory paragraph of proposed § 402.14(d). This paragraph governs initiation of early consultation by the Federal agency if the prospective applicant complies with paragraph (b).

Paragraph (d) of § 402.11 governs the procedures for conducting early consultation. To eliminate unnecessary regulatory language, this paragraph cross-references the items in § 402.14(c)-(j), since the general consultation requirements are the same as for formal consultation. The proposed rule repeated these requirements in § 402.14 (d) through (i).

One commenter argued that the Service exceeded its authority in proposed paragraph (d)(3) by telling Federal agencies how to meet their responsibilities by requiring Federal agencies to involve the applicant in the data-gathering function. Although this is not included in the final rule, the Federal agency has an underlying responsibility to involve the applicant in every aspect of the early consultation to the extent possible. Moreover, the applicant may be the primary source of data used in the consultation.

If the action is a major construction activity, then a biological assessment must be prepared in accordance with § 402.12 before the request for early consultation is submitted, as is required for formal consultation. This is a change from proposed § 402.12(b)(10), which made the biological assessment optional during early consultation. The Service agrees with the comment that, for major construction activities, a meaningful early consultation must include the preparation of a biological assessment because the preliminary biological opinion issued after early consultation may be confirmed as the final biological opinion. Therefore, if early consultation is requested for a major construction activity, the Federal agency must complete a biological assessment under § 402.12 prior to submitting its request for early consultation.

The time limits and extension provisions for formal consultation are incorporated by reference as the requirements for early consultation. Several commenters felt that the "mutually agreed upon" language of the proposal [§ 402.14(e)] was too loose and that definitive time limits were needed. The Service agrees and has adopted the time limits for formal consultation to apply to early consultation as well. The Service notes that, for major construction activities, the time period will not begin to run until the biological assessment under § 402.12 is completed. Because time deadlines have been

adopted, there is no need to require a written notice that consultation has been concluded, as requested by one commenter.

Proposed § 402.14(i) concerned requests by the Service for additional data, and did not require the addition of a written notice procedure for obtaining an extension. This is now required, as requested by one commenter, by incorporating the formal consultation requirements.

Proposed § 402.14(f) recognized that the Service's responsibilities during early consultation are the same as those that exist during formal consultation. The final rule retains this provision by reference. The Service is opposed to limiting the scope of its analysis of impacts during early consultation, and it is also opposed to limiting the free flow of communication among it, the Federal agency, and the applicant. Therefore, the comment suggesting that draft preliminary biological opinions not be released to the Federal agency or the prospective applicant is rejected. This is not an issue that can be dealt with on an ad hoc basis, depending on the program experience with particular agencies or regions. The policy behind early consultation is clear: full involvement of all parties, including the prospective applicant, to identify and eliminate conflicts at the earliest possible stage of a project.

Paragraph (e) of § 402.11 provides that the contents and conclusions of a preliminary biological opinion are the same as for a biological opinion issued after formal consultation in § 402.14(i). One commenter stated that biological opinions need only be issued after formal consultation under section 7(a)(2) of the Act and that this should be clarified in the rule. The Service disagrees because a "written statement" containing the Secretary's opinion is required to be given after the conclusion of both early and formal consultation. However, there is an important difference in these two types of opinions: the former has no independent, operative significance, while the latter states the Service's "final" judgment on the impacts of an action. The preliminary biological opinion, issued after the conclusion of early consultation, has no operative force until it is later confirmed by the Service under section 7(b)(3)(B) of the Act, just before the action is to be taken.

One commenter said that it is inappropriate to include an incidental take statement with a preliminary biological opinion. The Service believes that input on incidental take is essential to adequately assist the applicant in planning its action. It would be unfair to

force the applicant to wait until the time for confirmation of the preliminary biological opinion to receive its first notice on the terms and conditions that must be complied with and the amount and extent of permissible incidental take. No harm results to the species by providing this statement in the preliminary biological opinion because, as stated in the rule, it does not constitute a permit to take. The "taking" exemption under section 7(o)(2) does not occur until the preliminary biological opinion is later confirmed as a final opinion under § 402.11(f).

Paragraph (f) of § 402.11 is adopted from proposed §§ 402.15(b) and 402.18(a). This paragraph acknowledges that, if certain findings are made by the Service, a preliminary biological opinion may be confirmed as a final biological opinion after formal application for a Federal license or permit is made. The rule requires the Service to make its decision on confirmation within 45 days after receipt of the Federal agency's request. As requested by one commenter, both the request and the Service's response must be in writing.

Section 402.12 Biological Assessment.

This section explains the biological assessment requirements under section 7(c) of the Act and the process that must be followed in its preparation. The requirement that biological assessments be prepared in advance of certain consultations under section 7(a)(2) was added by the 1978 Amendments. Although the Service has, as a matter of agency practice, been requiring the preparation of biological assessments in appropriate cases under the authority of section 7(c), this final rule consolidates all regulatory requirements pertaining to biological assessments.

The proposed rule addressed the biological assessment provisions in §§ 402.01(c) and 402.12(b). In response to public comments, the Service has merged these sections in the final rule into § 402.12. The new format clarifies the requirements and procedures for preparing biological assessments. Although the organization of these provisions has been changed substantially, the substance of the regulation is, except for minor amendments, the same as that presented in the proposed rule.

The informal consultation and biological assessment processes were both presented in § 402.12 of the proposed rule. This confused several commenters who believed that biological assessments could only be performed in conjunction with informal consultations. To eliminate this

confusion, the biological assessment provisions are placed in a separate section, immediately before informal consultation. Although a Federal agency may prepare a biological assessment while involved in informal consultation with the Service, there is no requirement that it do so.

References to conference, early consultation, and formal consultation in proposed § 402.12 (b)(7) (third through fifth sentences) and (b)(10) have been deleted because cross-references to the biological assessment requirement have been inserted in §§ 402.10, 402.11, and 402.14 to explain the interrelationship of these processes.

The purpose of a "biological assessment," as stated in § 402.12(a), is to evaluate the potential effects of the action on listed or proposed species or designated or proposed critical habitat and determine whether any such species and habitat are likely to be adversely affected by the action. Biological assessments are designed to assist Federal agencies in "determining whether section 7(a)(2) consultation should be initiated by identifying endangered or threatened species that may be present in the area affected by their proposed project and by identifying the impacts of those projects on such species." H.R. Rep. No. 697, 96th Cong., 1st Sess. 14 (1979). Such assessments are designed to promote the "early discovery of and elucidation" of potential endangered and threatened species conflicts with proposed agency actions. These reviews should take place well before the agency exercises its discretion to authorize, fund, or carry out an action. H.R. Rep. No. 1625, 95th Cong., 2d Sess. 20 (1978).

One commenter asked that a reference be inserted for preparation of "preliminary biological assessments." The Service does not require advance review of draft biological assessments; the requested procedure would add to statutory requirements. Therefore, the addition has not been made.

Section 402.12(b)(1) of the final rule acknowledges that the Act exempts from the biological assessment requirement those actions for which contracts were let or construction was started on or before the effective date of the 1978 Amendments. One commenter argued that the assessment requirement must not be retroactive, but should apply only to current actions as of the issuance of the final rule. The Service must follow the Act on this point and adopt the rule as proposed. This will not operate to the disadvantage of any Federal agency involved in a section 7 consultation, because the Service has been requiring the preparation of

biological assessments since the effective date of the 1978 Amendments.

Section 402.12(b)(1) also recognizes that virtually any Federal agency, State or local agency, private organization, or individual (potential exemption applicants) may voluntarily prepare a biological assessment consistent with the procedures set forth in this section to assist it in fulfilling its section 7 responsibilities. One commenter urged the Service to delete the sentence referring to voluntary preparation of assessments in proposed § 402.12(b)(1) because consultation is terminated if a biological assessment is not required. The commenter's statement is only true for an action if no listed species or critical habitat are present in the proposed action area. The placement of that sentence in the proposed rule was confusing, and thus the final rule has been clarified. The Service would like to make it clear, however, that whether a biological assessment is required or voluntary bears no relation to whether a conference or formal consultation is required under §§ 402.10 or 402.14, respectively. The assessment is a tool used to identify impacts to species or habitat so that a decision can be made as to whether a proposed action is likely to adversely affect listed species or critical habitat. The biological assessment can be used to determine whether a conference or formal consultation is required.

The Act provides that any person who may wish to apply for an exemption from the requirements of section 7(a)(2) may voluntarily conduct such an assessment, in cooperation with the Service and under the supervision of the appropriate Federal agency. These potential exemption applicants must follow the procedures described in § 402.12. Under section 7(h)(2), an exemption is not permanent unless a biological assessment has been prepared. A permanent exemption remains in force for a particular Federal action regardless of the listing of additional species in the action area, whereas an ordinary exemption is limited to the species involved in the section 7 consultation. Paragraph (b)(1) acknowledges these statutory provisions.

Therefore, the Service retains the flexibility inherent in paragraph (b)(1) that allows for the preparation of biological assessments in those instances where they are not specifically required by this rule. Although requested by another commenter, the Service declines to set guidelines for the exercise of discretion by other Federal agencies or applicants

on the decision to voluntarily prepare assessments.

Paragraph (b)(2) has been added in response to public comments. The limitation in section 7(c)(1) of the Act on entering contracts or starting construction on an action while the preparation of a biological assessment is pending has been included in these regulations. This construction restriction applies to all actions involving the preparation of a biological assessment.

The fact that a biological assessment is not required for all actions does not mean that listed or proposed species or designated or proposed critical habitat receive less protection. Federal agencies still have an obligation to review all of their actions to determine whether formal consultation under § 402.14 is required. In addition, Federal agencies must confer on actions that are likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat.

One commenter asked that Federal agencies be required to document any finding of "no effect" on listed species or critical habitat for actions not involving the preparation of a biological assessment. The Service has no authority to impose such a requirement, but does encourage Federal agencies to use their NEPA documentation to illustrate their analysis of Endangered Species Act issues.

The Service reserves the right to request that an agency prepare a biological assessment. One commenter questioned the right of the Service to request assessments when such are not otherwise required by the Act. Another commenter feared that the Service would routinely request field studies with many of the characteristics of biological assessments, regardless of the action's potential effects, the acceptability of a general field reconnaissance, or the obligation of the Service to provide guidance and data. The Service's request for a biological assessment or for field studies is not of mandatory effect; a Federal agency may reject any such request. The Service recognizes that consultation involves a two-way flow of information. It will always strive to provide data that are available and to assist in designing or in conducting studies (within budgetary constraints and available staffing) or in gathering data through consultation.

Paragraph (c) of § 402.12 covers the request by a Federal agency for a species list from the Service. This paragraph was adopted from § 402.12(b)(1) (first sentence) of the proposed rule. Paragraph (d) of § 402.12

involves the Director's issuance of a species list. This paragraph was adopted from §402.12(b)(2) of the proposed rule.

The biological assessment process begins when a Federal agency decides that its action is a major construction activity, as discussed in these regulations, or it decides that it will voluntarily prepare a biological assessment. The Federal agency or the designated non-Federal representative requests information on whether listed or proposed species or designated or proposed critical habitat may be present in the action area. Within 30 days of receipt of that inquiry, the Director will respond with a list of any such species and critical habitat that may be present, as well as the available data (or references thereto). This may include recommendations for studies or surveys that may assist in the preparation of the biological assessment.

Contrary to the contentions of several commenters, the request for a species list is mandatory under section 7(c) for any major construction activity, unless the Federal agency forwards its own list for the Director's concurrence as explained below. This is not a burdensome requirement, even for apparent "no effect" actions, since the entire process, including the Director's response that no listed species or critical habitat occurs in the action area, may be carried out without delay through the NEPA process.

In response to comments, the final regulations explicitly allow the Federal agency or the designated non-Federal representative to proceed with the preparation of the biological assessment prior to receiving a species list from the Service. In this situation, the Federal agency or the designated non-Federal representative is required to notify the Director in writing as to the species and critical habitat that are being included in the assessment. As recommended by three commenters, the Service will respond to this notification in writing within 30 days as to whether it concurs with the species and critical habitat to be covered in the biological assessment.

One commenter suggested that an applicant should have an opportunity to informally request a species list to assist it during the planning stage of a project. Then, if the applicant begins preparation of a biological assessment within 90 days of receipt of this "informal" list, the commenter thought that the Service should not amend the list at a later time. The commenter appears to be advocating an opportunity for early consultation, which is provided for under §402.11 of this final rule.

Nevertheless, the request that a species list not be modified once issued

might backfire on the applicant, because §402.14 requires consultation on all listed species and critical habitat that may be affected by a Federal action. Even if a species is inadvertently omitted from the species list and biological assessment, the Act nevertheless requires that it must be considered in satisfying the requirements of section 7(a)(2). Thus, the sooner the Service notifies the applicant of additional species to be included in a required biological assessment, the sooner the consultation will be completed.

In addition to listed or proposed species or designated or proposed critical habitat, the Service will include candidate species in the species list. Candidate species are those species being considered for listing but not yet the subject of a proposed rule. This will inform the Federal agency and any applicant of potential proposals for listing. Candidate species have no legal status and are accorded no legal protection under the Act, and thus the Federal agency need not include them in a biological assessment. However, should a candidate species become proposed or listed prior to completion of the action, a conference or formal consultation may be required.

Several commenters asked that species lists be "site-specific" and not regional in scope. One of these commenters urged the Service to include only species actually known or believed to occur in the action area. The Service agrees that the species list should be tailored to the action area and that field personnel should take care that the list is not overinclusive. However, the Act requires the Service to provide a list of all listed or proposed species that "may be present" in the action area. Thus, migratory species that "may be present" at some point within the action area must be included in the species list.

Another commenter said that the Service should include only species in the list that it believes may be affected by the action. This approach is not consistent with section 7(c), which requires a disclosure of all species that "may be present" in the action area. The comment would also eliminate the Federal agency's right to make an initial evaluation of possible effects to each species.

One commenter's conclusion that a determination of no adverse effect after receipt of the species list, but before preparation of the assessment, eliminates the need to prepare the assessment and concludes consultation is erroneous. The biological assessment is used to determine whether an activity "is likely to adversely affect" listed

species or critical habitat. Consultation does not conclude unless the Service concurs in writing with the finding of the biological assessment indicating that the action is not likely to adversely affect listed species or critical habitat.

The Service has clarified paragraph (d)(1) to accommodate the concern of the House Committee that biological assessments not be required on major construction activities affecting proposed species or proposed critical habitat only. However, if a species list includes both listed and proposed species, each must be considered in the biological assessment as required by section 7(c) of the Act.

Concerned that the Federal agency should receive all information during the assessment process, one commenter asked that the species list be delivered to both the Federal agency and its designated non-Federal representative due to the agency's responsibility to supervise the preparation of the assessment. The Service declines to include this requirement in the rule, but will forward a copy to the Federal agency, if requested. It is the Federal agency's responsibility to decide whether it wants to designate a non-Federal representative, and if one is designated, the species list will be sent to the representative as requested by the Federal agency.

Several commenters suggested that the Service's ability to recommend "necessary" studies or surveys would contravene the "best available scientific and commercial data" standard of section 7(a)(2). The Service agrees that the proposed language may have implied that additional studies or surveys were required or necessary to complete the assessment. Therefore, the sentence is changed to state that the Service may recommend studies or surveys that it believes would assist in the preparation of the assessment. A new sentence is also added to clarify that such a recommendation is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act. This change preserves the Service's prerogative to request further studies if deemed appropriate, while recognizing the ultimate responsibility of the Federal agency to secure the best available data. Two commenters suggested that the request for studies be limited to studies necessary to locate and assemble already existing data. The Service declines to so limit the scope of studies it may request.

Paragraph (e) of §402.12 is carried over from §402.12(b)(3) of the proposal.

It requires a party preparing a biological assessment to verify its species list with the Service if, after 90 days from the receipt of or concurrence with the species list, it has yet to commence the preparation of the assessment. A written verification, as suggested by one commenter, is not required since that would be tantamount to issuing a second species list, contrary to the informal nature of this verification step. The Federal agency may, on its own, document the verification received under this paragraph in its administrative record. As requested by one commenter, the Service has distinguished the initiation of the biological assessment time period (time of receipt of or concurrence with a species list) from the point at which actual preparation of the assessment is begun.

Based on comments received, a new paragraph (f) entitled "contents" has been added. Some commenters argued that Federal agencies should be required to include certain minimum research methods or activities in the preparation of a biological assessment. One commenter suggested that preparers of biological assessments should:

(a) conduct a scientifically sound on-site inspection of the area affected by the action, which must, unless otherwise directed by the Service, include a detailed survey of the area to determine if listed or proposed species are present or occur seasonally and whether suitable habitat exists within the area for either expanding the existing population or potential reintroduction of populations;

(b) interview recognized experts on the species at issue, including those within the Fish and Wildlife Service, the National Marine Fisheries Service, State conservation agencies, universities and others who may have data not yet found in scientific literature;

(c) review literature and other scientific data including recovery plans if available to determine the species' distribution, habitat needs, and other biological requirements;

(d) review and analyze the effects of the action on the species, in terms of individuals and populations, including consideration of the indirect and cumulative effects of the action on the species and habitat;

(e) analyze alternate actions that may provide conservation measures; and

(f) conduct any studies necessary to fulfill the requirements of (a) through (e) above.

The Service agrees that assessments should be as complete and thorough as possible, but declines to impose strict minimum standards that all biological assessments must satisfy. The above-listed activities, which may be performed in preparing an assessment, are endorsed by the Service as items that a model assessment would include. However, the nature of the Federal action may not warrant carrying out all

of these research activities or studies, and some of the steps may not be technologically feasible in certain cases. Therefore, the new paragraph (f) only contains suggestions of what a Federal agency may include in a biological assessment.

One commenter asked the Service to explain the difference between the degree of information needed in a biological assessment and the degree of information needed to initiate formal consultation when the action does not require the preparation of an assessment. In both cases the overall information standard is the same: "best scientific and commercial data available." The difference arises in the process. If a biological assessment is prepared, it must include not only the data but also a synthesis of the data involving an analysis of the effects of the action. Basically, the assessment serves as an analytical instrument and can be used by the Federal agency "to build its case" as to whether a particular action is likely to adversely affect a listed species or its critical habitat. If the Service concurs with a determination of "not likely to adversely affect," then formal consultation is not required. If an assessment is not required, the Federal agency need only submit data to the Service to initiate formal consultation pursuant to § 402.14(c).

Paragraph (g) of § 402.12, which deals with the authority to incorporate earlier biological assessments by reference as the assessment for a current proposal, is adopted from the last two sentences of proposed § 402.12(b)(1). In those instances where a proposed Federal action is identical, or very similar, to a previous action for which a biological assessment was prepared, the Federal agency may not need to prepare a new biological assessment.

One commenter requested that language be added to clarify that a previous biological assessment being incorporated by reference could have been part of a prior EIS or area-wide assessment. The Service declines to make the change noting that the form of the previous biological assessment (whether in an EIS or other document) has no bearing on whether it meets the conditions for incorporation by reference.

In response to comments, the conditions that must be met for incorporation by reference are clarified. The biological assessment requirement may be fulfilled by incorporating by reference the earlier biological assessment and supporting data into a written certification that: (1) the proposed action involves similar impacts to the same species in the same

geographic area; (2) no new species have been listed or proposed or critical habitat designated or proposed for the action area; and (3) the biological assessment has been supplemented with any relevant changes in information.

Condition (1) has been expanded to allow incorporation by reference if the proposed action involves similar impacts (rather than no new impacts). The term "or administrative unit" has been deleted as it is substantially the same as "geographic area." The Service adds "for the action area" at the end of condition (2) to clarify the scope of the certification. Finally, condition (3) is changed to allow Federal agencies to incorporate a former biological assessment by reference while supplementing it with any relevant changes in information. This change clarifies the intent behind this paragraph.

Paragraph (h) of § 402.12, which cross-references permit requirements under the Act that may apply to the preparation of a biological assessment, is adopted as proposed in § 402.12(b)(4)(i). The Service believes that the references in the rule are adequate to alert Federal agencies and/or designated non-Federal representatives of the need to consider applicable permit requirements, rather than include the appropriate section 10 permit requirements in these regulations, as suggested by one commenter. Certain field work might involve the take (*i.e.*, harassment, harm, etc.) of listed species which, absent a permit, would violate sections 9 or 4(d) of the Act. To avoid possible violations, the Federal agency or non-Federal representative should apply for and obtain a section 10 permit for such field work. Those individuals carrying out field studies or other research without a permit during the section 7 consultation process are subject to the prohibitions of the Act and other applicable wildlife laws. The Service emphasizes that permits should be obtained if takings of any listed species are anticipated.

Paragraph (i) of § 402.12 specifies the time period for completing a biological assessment and sets out the requirements for any needed extension. This paragraph is taken substantially from § 402.12(b)(6) of the proposed rule.

Two commenters asked that the rule require written notices of all extensions, regardless of whether an applicant is involved. A written notice from the Federal agency to the applicant is required if an extension is agreed upon between the Service and the Federal agency, and such written notice must be provided by the Federal agency prior to

the expiration of the 180-day time period. However, the Service declines to require a written notice if an applicant is not involved in the consultation, because responsibility for the preparation and completion of the biological assessment rests with the Federal agency. The Service will defer to the needs and judgment of the Federal agency which can document the extension in its administrative record.

Another commenter asked that the Service explain that the 180-day time period begins on the date of receipt of the species list (or the date of receipt of the Director's concurrence with the Federal agency species list). This change has been made since it clarifies when the time period begins and is consistent with the intent of this paragraph.

As noted above, if an applicant is involved, the 180-day period may not be extended unless the agency provides the applicant, before the close of the 180-day period, with a written statement setting forth the estimated length of the proposed extension and the reasons why an extension is necessary. The applicant has no remedy to expedite the preparation of the biological assessment under section 7(c) of the Act. Thus, the 180-day time period is subject to an indefinite extension at the Federal agency's prerogative. The Service lacks statutory authority to impose an appeal process to review extensions, as requested by two commenters.

Paragraph (j) of §402.12, which requires the submission of completed biological assessments to the Director for review, is adopted from proposed §402.12(b)(4)(iii). In response to two comments, the Director will make a written response within 30 days after receiving the complete assessment as to whether or not the Service concurs with the findings in the assessment. This change provides Federal agencies with a written record acknowledging the Service's receipt of the biological assessment and indicating the results of the Service's review.

A new sentence is added to this paragraph to clarify that the Federal agency may initiate formal consultation concurrently with the submission of the assessment to the Director.

In response to one comment, the Service declines to substitute "Service" for "Director" in this paragraph. It is important that the Director or his authorized representative directly receive the biological assessment for review so that a timely review can be facilitated.

Paragraph (k) of §402.12, governing the use of a completed biological assessment, is derived from §402.12(b)(7) of the proposed rule. Once

the biological assessment has been completed, the Federal agency must consider whether formal consultation should be initiated or if a conference is necessary. Three commenters noted that a written notice of concurrence should be issued by the Director if the Service agrees with the Federal agency's finding that its action is not likely to adversely affect listed species or critical habitat (*i.e.*, the Service concurs in writing that formal consultation is not needed). This comment has been accommodated by appropriate changes to paragraphs (j) and (k).

The proposed §402.12(b)(5), "Assistance from other sources," has not been included in the biological assessment section of the final rules. The substance of this paragraph has been included in the final §402.08 dealing with designated non-Federal representatives. The first two sentences have been deleted since a Federal agency may obtain assistance from any source to aid in the preparation of a biological assessment (or other aspect of consultation), and it does not need to be authorized in these regulations. One commenter suggested that the Service be included as a source of information; however, assistance from the Service is already included in appropriate sections of the regulations.

Section 402.13 Informal Consultation.

Informal consultation is an optional procedure that includes all contacts between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required. It is designed primarily to except from the formal consultation process those proposed actions which, upon further informal review, are found not likely to adversely affect a listed species or critical habitat. If the Service concurs with such a determination, formal consultation is not required. The final rule is adopted largely by combining proposed §§ 402.12(a), 402.15(c), and 402.15(i)(1), into one composite statement of the purpose and scope of informal consultation.

Several commenters disagreed on the scope of informal consultation. One commenter felt that informal consultation should include all dialogue between the Service, the Federal agency, and any designated non-Federal representative in determining whether formal consultation is required. Another commenter recommended that informal consultation be available if listed species are found in the action area. The Service believes that informal consultation encompasses all of these communications between the Service,

the Federal agency, and the designated non-Federal representative, as well as others. The Service is available for informal consultation at any time; the decision on whether to seek informal consultation is that of the Federal agency. The Service agrees that, if requested as a part of informal consultation, it should participate in NEPA scoping meetings.

The Service declines to specify uniform levels of contact that must be followed in conducting informal consultations. Existing relationships between the Service's field or regional offices and particular Federal agencies mandate maximum flexibility. The present system is working well and efficiently addresses the needs of other Federal agencies, and it is therefore retained.

Because informal consultation is an optional process that is under the control of the Federal agency as to its initiation and duration, the Service declines to require notices of initiation and/or termination. Such a step would merely place paperwork burdens on the Federal agency in an otherwise voluntary process.

As noted in §402.12, biological assessments are required for major construction activities. To clarify a procedural point, the Service notes that the biological assessment process may be conducted simultaneously with informal consultation if desired by the Federal agency, or the Federal agency may choose to undertake the biological assessment without any informal consultation. Whether or not a biological assessment is required, the Federal agency may choose to enter into informal consultation.

In response to many comments, the Service has made numerous adjustments throughout these regulations to eliminate references to informal consultation as a prerequisite to formal consultation. The Service agrees that such a process would not be workable, both as a result of limited consultation resources and the need to respect Federal agency program discretion. As previously noted, the proposed rule required formal consultation if the action "may adversely affect" listed species or critical habitat. "Beneficial" actions were excused from formal consultation if the Service concurred during the mandatory informal consultation. Since informal consultation has been made strictly an optional process in this final rule, the Service retains, from the 1978 rule, the "may affect" trigger for formal consultation in §402.14 of the final rule.

Under this final rule, if a Federal agency determines that its action "may affect" listed species or critical habitat, then formal consultation is required unless an exception applies. One exception is that a Federal agency may, through informal consultation, utilize the expertise of the Service to evaluate the agency's assessment of potential effects or to suggest modifications to the action to avoid potential adverse effects. If, as a result of informal consultation, the Federal agency determines, and the Service concurs, that the action (or modified action) is "not likely to adversely affect" listed species or critical habitat, then formal consultation is not required. The consultation process would terminate with the written concurrence of the Service. Therefore, through this informal consultation process, those activities which are found to have beneficial, discountable, or insignificant effects upon listed species or their critical habitats could be deemed to be in compliance with section 7(a)(2) without formal consultation. If a "not likely to adversely affect" determination cannot be made during informal consultation, then formal consultation is required for those Federal actions that "may affect" listed species or their critical habitat.

In short, the final rule retains the general requirement for formal consultation if the Federal agency determines that its action "may affect" listed species or critical habitat. The Federal agency may, however, through voluntary informal consultation with the Service, forego formal consultation and promptly implement actions that the agency and the Service agree are not likely to adversely affect listed species or critical habitat. The Service finds that this reformulation of the consultation process is not significantly different from the current practice, except that, as a result of informal consultation, biological opinions will no longer be required for actions that "are not likely to adversely affect" listed species or critical habitat.

The Service could not accommodate all concerns expressed on this issue. Two commenters contended that the "may adversely affect" standard for initiating formal consultation yielded too much discretion to action agencies. They stated that such a threshold would shift the benefit of the doubt from one in favor of the listed species to one in favor of the Federal agency's action. Noting the Service's expertise on wildlife issues, the commenter urged the Service to reverse this shift. As noted above, the Service did not intend to reverse the burden of proof with the focus on

"adverse effects." The goal is to reduce procedural barriers for actions which the Service believes are not likely to have an adverse effect, while retaining full protection for listed species or critical habitat. The changes noted above address these commenters' concern. However, other commenters who suggested a shift in the burden of proof cannot be accommodated. The commenters that urged a "would adversely affect" standard for triggering formal consultation, a standard that might be interpreted as requiring a showing of effects that destroy or adversely modify critical habitat or are likely to jeopardize the continued existence of listed species, are requesting a trigger for formal consultation that the Service believes is too close to the "jeopardy" standard of section 7(a)(2). The threshold for formal consultation must be set sufficiently low to allow Federal agencies to satisfy their duty to "insure" under section 7(a)(2). Therefore, the burden is on the Federal agency to show the absence of likely, adverse effects to listed species or critical habitat as a result of its proposed action in order to be excepted from the formal consultation obligation.

The Service believes that informal consultation is extremely important and may resolve potential conflicts (adverse effects) and eliminate the need for formal consultation. Through informal consultation, the Service can work with the Federal agency and any applicant and suggest modifications to the action to reduce or eliminate adverse effects. If a Federal agency modifies its action so that the action is not likely to adversely affect listed species or critical habitat, then formal consultation is not required.

Section 402.14 Formal Consultation.

These regulations require Federal agencies to review their actions to determine whether they "may affect" listed species or critical habitat. Formal consultation procedures must be initiated if such a situation exists, unless, with the written concurrence of the Service, the Federal agency determines through informal consultation and/or through the biological assessment process that its action is not likely to adversely affect listed species or critical habitat. As noted above in regard to § 402.13, the final rule adopts the "may affect" standard of the 1978 rule, with a special provision allowing actions "not likely to adversely affect" to by-pass the formal consultation process as a result of informal consultation with the Service.

Paragraph (a) of § 402.14 sets out the requirements for formal consultation. This paragraph is a composite of

paragraphs (a) and (k) of proposed § 402.15. Paragraph (b), which sets out the exceptions to the initiation requirement of (a), was taken primarily from proposed §§ 402.12(b)(7) and 402.15 (b) and (c).

The Service declines to substitute "may" for "shall" in describing the Federal agency's responsibilities in paragraph (a), as requested by one commenter. Federal agencies have an obligation under section 7(a)(2) of the Act to determine whether their actions may affect listed species and whether formal consultation is required under these regulations. However, the Service does not intend to mandate the timing of this review, which is solely at the discretion of the Federal agency. Early review of its actions is to the advantage of the Federal agency so that compliance with section 7 can be attained without undue delays to its action.

Paragraph (a) also includes a provision for the Director to request a Federal agency to enter into consultation. Two commenters asked that the final rule empower the Director to require a Federal agency to consult. Although the Service will, when appropriate, request consultation on particular Federal actions, it lacks the authority to require the initiation of consultation. The determination of possible effects is the Federal agency's responsibility. The Federal agency has the ultimate duty to ensure that its actions are not likely to jeopardize listed species or adversely modify critical habitat. The Federal agency makes the final decision on whether consultation is required, and it likewise bears the risk of an erroneous decision.

The last sentence of proposed § 402.15(a), dealing with Service assistance to Federal agencies, has been deleted as it is more appropriately addressed in the preamble. The Federal agency may obtain information and advice from the Service, but this is a supplement to, and not a substitute for, formal consultation. The Service believes that there should be a continuous dialogue between the Service and the Federal agency involving the exchange of information and assistance as part of the formal consultation.

Unless a Federal agency chooses to avail itself of the exceptions in paragraph (b), it must initiate formal consultation if its proposed action "may affect" listed species or critical habitat. Any possible effect, whether beneficial, benign, adverse, or of an undetermined character, triggers the formal consultation requirement, as suggested

by one commenter. However, although informal consultation is not required, a Federal agency may use that process and/or the biological assessment process to remove an action that "is not likely to adversely affect" listed species or critical habitat from the formal consultation requirement.

Proposed paragraph (c), a "no adverse effect" exception, was attacked as weakening the Act. One commenter remarked that this procedure unrealistically allows Federal agencies to determine the presence of a "detrimental effect," through informal consultation, when the precise objective of formal consultation is to reach that same goal. The Service does not agree, because formal consultation is conducted to determine if an action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. Adverse effects may exist without constituting jeopardy. However, the Service has changed the trigger for formal consultation to "may affect" with certain exceptions contained in paragraph (b).

The exceptions in paragraph (b) are derived from the "will not adversely affect" exception in proposed § 402.15(c) and from the confirmation of the preliminary biological opinion in proposed § 402.15(b). The first exception is modified to "not likely to adversely affect" to make the biological assessment provisions compatible with the formal consultation provisions. Under section 7(c) of the Act, a biological assessment is completed to facilitate compliance with the consultation provisions of section 7(a)(2) by identifying whether any species or critical habitat is "likely to be affected." If the Federal agency determines, with Service concurrence, that its action is not likely to adversely affect any listed species or critical habitat, there is no need for formal consultation.

Imposing the time delays and information responsibilities of formal consultation on such actions would not provide any additional protection to listed species or critical habitat and may discourage interagency cooperation. Regulatory flexibility is appropriate here to eliminate undue burdens. By requiring the Service's "written concurrence" with a "not likely to adversely affect" finding as a prerequisite to invoking the exception to formal consultation, the Service believes it has retained adequate review authority through informal consultation. If the information made available during informal consultation is not sufficient to make this determination, formal consultation

is required. The case of *Romero-Barcelo v. Brown*, 643 F.2d 835 (1st Cir. 1981), *rev'd on other grounds sub nom. Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982), does not preclude this change. That decision interpreted the 1978 rule but did not set a minimum threshold for initiation of formal consultation under the Act. Paragraphs (a) and (b), as adopted, are totally within the statutory authority of the Service.

The other exception to the general formal consultation requirement is the confirmation of a preliminary biological opinion as the final biological opinion. If early consultation takes place, the Service will issue a preliminary biological opinion. When the prospective applicant applies for a Federal permit or license, the Federal agency may request that the Service confirm the preliminary biological opinion as the final biological opinion that would have been issued after formal consultation. If the Service reviews the proposed action and finds no significant changes in the action as planned and no significant changes in the information used during early consultation, such a confirmation will be issued. Consultation is required if the preliminary biological opinion is not confirmed.

Paragraph (c) of § 402.14 specifies the required contents of a request for formal consultation. This paragraph is adopted substantially from proposed §§ 402.12(b)(7) and 402.15(d).

According to one commenter, the information requirements of paragraph (c), which apply to all actions involved in formal consultation, lack statutory authority. The Service cites the obligation to use the "best scientific and commercial data available" and the overall responsibility to consult in good faith under section 7(a)(2) as ample authority for the information requirements. Proposed item (vi), requiring a list of Federal agencies that have jurisdiction in the action area and how they may be affected, is too broad since much of this information would be unrelated to the consultation. Other Federal actions that are interrelated or interdependent would be discussed along with the effects of the action. Therefore, this item is not included in the final rule. The remaining items are essential in determining the parameters of the action, the extent, duration, and severity of its impacts, and the effects of other actions in the action area. The Service retains these essential information requirements, although it has noted under subparagraph (5) that only "relevant" reports, including

environmental impact statements, etc., need be supplied, because consultations will in most cases be completed prior to the production of final NEPA documentation for the subject action.

The concluding sentences of paragraph (c) permit Federal agencies, subject to the Director's approval, to tailor their requests for consultation to a particular segment of a comprehensive plan, so long as the effects of the action as a whole are considered. To clarify this passage, as requested by one commenter, the Service uses the example of the management, pursuant to a comprehensive plan, of a National Wildlife Refuge that is inhabited by a listed species. Section 7 consultation may be undertaken on a segment of that management program, such as big-game hunting, and a biological opinion will be issued on that phase of the program only. However, in formulating its biological opinion, the Service must consider the effects, including indirect effects, of the action as a whole, and cumulative effects of unrelated management programs in reaching the conclusion of "jeopardy" or "no jeopardy." The concluding passage of paragraph (c) illustrates the flexibility inherent in the formal consultation process and the care with which the protections of section 7 are preserved.

Paragraph (d) of § 402.14 repeats the required information standard of section 7(a)(2): "best scientific and commercial data available." This paragraph is adopted essentially without change from proposed § 402.15(d)(2), except that, pursuant to public comment, the Service changed "biological information" to "scientific and commercial data" to bring the language of the regulation in line with the Act. One commenter suggested that the phrase "or which can be developed during the consultation process" be removed from this paragraph. The Service has modified the wording to state that the information referred to in this paragraph is information that can be obtained during the consultation. We believe that information could become available at any time during the consultation, and such information should be submitted to the Service for its consideration. The legislative history of the 1979 Amendments supports this provision. H.R. Conf. Rep. No. 697, 96th Cong., 1st Sess. 12 (1979). The Service is satisfied that this paragraph adequately mandates the use of the best available scientific and commercial data, requires Federal agencies to supply this data at any time during formal consultation, and recognizes that this information requirement is a Federal agency

responsibility—not an obligation of the Service.

Paragraph (d) of § 402.14 also adopts a portion of § 402.15(d)(3) of the proposed rule that requires the Federal agency to provide any applicant with the opportunity to participate in formal consultations, including submitting information for consideration during the consultation. The remainder of proposed § 402.15(d)(3) was deleted because it duplicated other parts of the final rule.

Paragraph (e) of § 402.14 establishes the time period for conducting formal consultations and explains the process for extending the consultation period. The paragraph is adopted substantially as proposed in § 402.15(e), with certain technical, clarifying amendments.

The Amendments changed the timing requirement on the conclusion of formal consultation from the 60 days originally established by the 1978 rule to a maximum of 90 days or to such time periods as discussed below. If an applicant is involved, the Service and the Federal agency may mutually agree to extend consultation for up to 60 additional days without the consent of the applicant, provided that the Service submits to the applicant, before the close of the initial 90-day period a written statement setting forth (1) the reasons why a longer period is required, (2) the information that is required to complete the consultation, and (3) the estimated date on which the consultation will be completed. A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. The biological opinion must be delivered to the Federal agency and any applicant promptly after the conclusion of formal consultation (within 45 days).

One commenter suggested that a provision be added that would require the Service to issue a notice concluding formal consultation with a finding that it has sufficient information to prepare a biological opinion. The Service declines to adopt this comment. At the end of the 90-day period (unless extended), the parties to the consultation realize that the Service has but 45 days to deliver its biological opinion to the Federal agency and any applicant. A mandatory notice of "sufficient information" might be, in some cases, misleading by creating the impression that additional information or studies may not be advisable. The Service must develop its biological opinion based upon the best scientific and commercial data available regardless of the "sufficiency" of that data. Therefore, the suggested change does not accurately reflect the legal

framework within which the Service must operate.

The Service has defined the statutory directive to issue biological opinions "promptly after" the conclusion of formal consultation as requiring the delivery of a biological opinion to the Federal agency and any applicant within 45 days. Several commenters agreed with this stipulated deadline as long as the applicant retains some control over extensions. Other commenters felt that the 45-day period was excessive, and they argued that the opinion drafting period should either be worked out with mutually-agreeable extensions or the opinion should be issued by the end of the consultation period. The Service retains the 45-day drafting period as consistent with the statutory requirement and as a necessary time period to further refine biological opinions after the conclusion of formal consultation.

One sentence has been added to paragraph (e) to acknowledge the ability of the Service and the Federal agency, where no applicant is involved, to extend consultation for a mutually-agreeable time period. This clarification satisfies the request of one commenter.

Paragraph (f) of § 402.14, which governs Service requests for additional information, is adopted from § 402.15(j)(1) of the proposed rule. The Service declines to rename this paragraph "extension of consultation" because that topic is generally covered in paragraph (e).

In some cases, the Service may determine that additional information would enhance the formulation of its biological opinion. To cover this situation, the final rule adopts the procedures discussed by Congress in the legislative history of the 1979 Amendments. S. Conf. Rep. No. 697, 96th Cong., 1st Sess. 12 (1979). When additional data is believed to be advantageous, the Service will request an extension of formal consultation. When the Service requests such an extension, it will identify the types of additional data sought for assisting consultation. The Service will, to the extent practicable, and within existing budgetary and personnel restrictions, provide assistance in planning studies, furnishing relevant data, and providing recommendations that may be necessary to obtain the additional data. The responsibility for conducting and funding any studies, however, belongs to the Federal agencies or the applicant and not to the Service.

The comments received on this paragraph covered a wide spectrum of opinion as to the breadth of the

Service's authority to request additional data. Some commenters questioned the statutory authority of the Service under this provision, and they erroneously interpreted the Service's ability to request additional data as the authority to require an extension of formal consultation to obtain such data. Their position was that additional data was not a valid reason for seeking an extension of formal consultation and that additional data should only be sought when obtaining it would not delay the consultation and when the Service is willing to fund the studies. Another commenter went further, suggesting that the request for additional data be treated as an extraordinary measure that should be invoked "reluctantly and only on rare occasions." The commenter said that the Service should affirmatively state that existing data is presumed to be adequate and that the Service bears the burden of demonstrating inadequacy before seeking additional data.

On the other end of the spectrum, several commenters faulted the Service for not requiring an extension so that additional data could be obtained under this paragraph. Citing the Federal agency's statutory duty to use the "best scientific and commercial data available" and the decision in *Roosevelt Campobello International Park Commission v. EPA*, 684 F.2d 1041 (1st Cir. 1982) ("Pittston case"), these commenters noted that Federal agencies are required by section 7(a)(2) to do "all that [is] practicable" to develop information for the consultation. *Pittston case, supra*. According to the commenters, the proposed rule gave too much discretion to Federal agencies in controlling the information used in the consultation process.

The Service adopts the proposed rule because it recognizes the need for an opportunity to request additional data while deferring to the Congressional intent that consultation have a definite end point. Additional data may be requested by the Service, but the Service is not relieved of its duty to issue a biological opinion unless appropriate time extensions are obtained under paragraph (e).

However, Federal agencies and applicants are cautioned that they bear the burden under section 7(a)(2) to show that they have obtained the best available scientific and commercial data. This is not the Service's burden or obligation, but the Service does have the responsibility to alert the Federal agency and any applicant of areas where additional data would provide a better information base from which to

formulate a biological opinion. This advice from the Service is intended to help the Federal agency to better satisfy its duty to insure that its action is not likely to jeopardize listed species or adversely modify critical habitat.

A Service request for additional data will not be used as a vehicle for burdening applicants with unnecessary studies and inordinate delays, as feared by one commenter. As in the *Pittston* case, these requests will be limited to readily obtainable data that would assist the Service in formulating its biological opinion. In paragraph (f), as in *Pittston*, a distinction must be made between requests for special research projects and requests for routine, customary data collection activities. Moreover, paragraph (f) does not take the final decision regarding the acquisition of additional data away from the Federal agency. The agency still has the discretion to reject the Service's request for additional data provided it is not arbitrary or capricious in doing so. The paragraph has been clarified to state that the Federal agency, when collecting additional data, shall do so to the extent practicable and within the timeframe of the agreed upon extension.

The Service, in requesting additional data, will not comment as to the overall adequacy of the Federal agency's data. It is the agency's burden to obtain credible data. The Service's request for additional data, just as the Federal agency's inability to complete any agreed upon collection of data, should not be interpreted as evidence that the Federal agency has failed to meet the information standard of section 7(a)(2); it would merely represent the Service's belief that the additional data would improve the consultation data base so that it could issue the best biological opinion possible. The Service, therefore, has added language to the final rule to clarify this provision.

As discussed above, if an extension is not agreed to in accordance with paragraph (e), the Service shall issue a biological opinion based on the best scientific and commercial data made available during the consultation. The Conference Report to the 1979 Amendments states that in this situation, the Federal agency has a continuing responsibility to make a reasonable effort to develop additional data. H.R. Conf. Rep. No. 697, 96th Cong., 2d Sess. 12 (1979). By initiating informal consultation with the Service at an early stage of the development of a proposed action, the Federal agency would, in most cases, minimize the need

to request an extension of formal consultation because of a lack of data.

In formulating its biological opinion, the Service must provide the "benefit of the doubt" to the species concerned, H.R. Conf. Rep. No. 697, *supra*, at 12. In addition, a biological opinion must be developed within the consultation timeframe based upon the best scientific and commercial data available. Though requested by several commenters, the Service is not authorized to condition its "no jeopardy" opinions with "safeguards" or to issue "may jeopardize" opinions in retaliation for an agency refusal to extend consultation or to develop additional data.

The Service was requested to publish availability notices for biological opinions to facilitate public participation in the conservation of listed species. For the reasons noted previously in response to a general comment, the Service declines to impose such a requirement on itself as an amendment to paragraph (f).

Paragraph (g) of § 402.14, which sets out the Service's responsibilities during formal consultation, is adopted from proposed § 402.15(f) with only minor changes to clarify the Service's responsibilities. The public comments concerning paragraph (g) focused on the fifth item: the responsibility to discuss the availability of reasonable and prudent alternatives. The Service is committed to working closely with Federal agencies and any applicants in the development of reasonable and prudent alternatives. However, the Service is unable to agree that a draft reasonable and prudent alternative should be excluded from the biological opinion if the Federal agency disagrees as to its reasonableness, as suggested by one commenter. The Service will, in most cases, defer to the Federal agency's expertise and judgment as to the feasibility of an alternative. Nevertheless, in those instances where the Service disagrees with a Federal agency's assessment of the reasonableness of its alternatives, the Service must reserve the right to include those alternatives in the biological opinion if it determines that they are "reasonable and prudent" according to the standards set out in the definition in § 402.02; the Service cannot abdicate its ultimate duty to formulate these alternatives by giving Federal agencies control over the content of a biological opinion.

Paragraph (g) provides for Federal agency and applicant review of the basis for any finding contained in draft biological opinions, including the availability of reasonable and prudent

alternatives. Four commenters requested that the final rule clarify whether an applicant was entitled to receive a copy of the draft biological opinion. The Service believes that the applicant should participate in the review and should receive a copy of the draft opinion from the Federal agency. The final rule includes this provision.

The release of draft opinions to Federal agencies and any applicants (through the Federal agency) facilitates a more meaningful exchange of information. Review of draft opinions may result in the development and submission of additional data, and the preparation of more thorough biological opinions. Two commenters opposed the release of draft biological opinions. Although they were supportive of open communication and mediation between the Service and the Federal agency during the consultation time period, the commenters opposed Federal agency review of draft opinions because agencies could bring pressure on the Service to modify a particular reasonable and prudent alternative or to convert the opinion's conclusion from "jeopardy" to "no jeopardy." If there were any discussions needed regarding the reasonable and prudent alternatives, noted the commenters, this could be done in "further discussion" after the issuance of the biological opinion. The Service disagrees that Federal agency review of draft biological opinions will result in "rewritten" biological opinions, unless valid biological reasons mandate a change. Federal agency review of draft opinions helps ensure the technical accuracy of the opinion, and may save time and resources by resolving these issues early. The Service believes that the availability of draft biological opinions is a meaningful process and has retained it in the final rule. As noted previously in the "Definitions" section, "further discussion" has been deleted from this rule. Thus, through the discussions between the Service and the Federal agency and any applicant during formal consultation and the provision to review draft biological opinions, the exchange of information for the development of reasonable and prudent alternatives is sufficient.

The proposed rule stated that the 45-day deadline for delivery of the final biological opinion would be suspended while the Federal agency retained the draft opinion. Several commenters complained that such a suspension would violate the statutory deadlines for concluding formal consultation and that the applicant would be powerless to force an end to the consultation. Although the proposed rule provided

that, "[i]f the draft biological opinion is not returned to the Service within a reasonable period of time, the Service will issue a final biological opinion," the Service agrees that the meaning of "a reasonable period of time" requires clarification. Therefore, to accommodate these comments, the Service now requires the Federal agency to secure the applicant's written consent to an extension for a specified time period if the 45-day deadline is to be suspended while the draft opinion is under review. If no extension is agreed to, the biological opinion will be issued within 45 days of the conclusion of formal consultation.

Another commenter suggested that the Service be required to deliver its biological opinion within the Federal agency's NEPA timeframe so that the biological opinion can be included without delaying the release of the agency's NEPA document. The Service will attempt to coordinate all environmental reviews with the consultation. However, special timing problems under other Federal statutes, or failure to enter into the consultation process early in the planning stage of an action, is not a justification for altering the required timeframe established under the Act. If a particular Federal agency needs special procedures to handle its consultation responsibilities, the Service urges the development of counterpart regulations under §402.04.

Paragraph (g) has also been modified to reflect that the Service, in formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions taken by the Federal agency or applicant including any actions taken prior to the initiation of consultation.

Paragraph (h) of §402.14, which deals with the contents of a biological opinion, is adopted with minor, technical corrections from proposed §402.15 (g)-(h). The final rule distinguishes that information or material which will be included in a biological opinion from that which will be provided with a biological opinion.

The biological opinion will include: (1) a summary of the information on which the opinion is based; (2) a detailed discussion of the effects of the action on listed species or critical habitat; and (3) the Service's opinion as to whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. The biological opinion will conclude that either: (1) the action is not likely to

jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion), or (2) the action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy" biological opinion).

If a "jeopardy" biological opinion is issued, the Service must identify and include reasonable and prudent alternatives, if any, that will avoid jeopardy and that the Federal agency or applicant can implement. If the Service is unable to develop reasonable and prudent alternatives, it will indicate that, to the best of its knowledge, there are no such alternatives that would satisfy the standard of section 7(a)(2).

Paragraph (i) of §402.14, which governs incidental taking under section 7(b)(4) of the Act, is adopted essentially as proposed in §402.19. This paragraph is included in the formal consultation section of the final rule because of the direct relationship between final biological opinions and incidental take statements.

The 1982 Amendments changed section 7(b) to include provisions concerning incidental taking of species. The new provisions included in sections 7(b)(4) and 7(o)(2) of the Act are designed to resolve the situation where a Federal agency or an applicant has been advised, through a biological opinion, that the proposed action or the adoption of the reasonable and prudent alternative(s), will not violate section 7(a)(2) of the Act, but the proposed action (or adopted alternative) will result in taking individuals of a listed species incidental to the action. The new provision states that, if the action complies with specified terms and conditions, the resulting incidental take will not be a violation of any "taking" prohibitions established by section 4(d) or 9(a)(1) of the Act.

As noted in the public comments, the availability of an "incidental" taking exemption through the section 7 consultation process is a welcome clarification made by the 1982 Amendments. However, many commenters requested additional guidance on this subject, and several felt that the proposed rule was cumbersome and burdensome. The Service believes that the following discussion will clarify the incidental take provision and explain the incentives for compliance with sections 7(a)(2) and 7(b)(4) of the Act.

If an agency action receives a "no jeopardy" biological opinion, or if the Federal agency adopts any reasonable

and prudent alternative provided in a "jeopardy" biological opinion, then the action may proceed in compliance with section 7. An incidental take statement will be provided with the biological opinion when the activity may incidentally take individuals of a listed species but not so many as to jeopardize their continued existence. If the action proceeds in compliance with the terms and conditions of the incidental take statement, then any resulting incidental takings are exempt from the prohibitions of section 4(d) or 9 of the Act. No permit is required of the Federal agency or any applicant in carrying out the action, as one commenter contended. The biological opinion, plus the incidental take statement, operate as an exemption under section 7(o)(2) of the Act. However, this exemption is limited to actions taken by the Federal agency or applicant that comply with the terms and conditions specified in the incidental take statement. Compliance with these terms and conditions is mandatory to qualify for the exemption from section 4(d) or 9 of the Act. "Actions that are not in compliance with the specified measures . . . remain subject to the prohibition against takings that is contained in section 9." S. Rep. No. 418, 97th Cong., 2d Sess. 21 (1982). Therefore, the Service cannot make these terms discretionary, as urged by one commenter.

Paragraph (i)(1) states that, where incidental takings may occur, the Service will provide with the biological opinion to the Federal agency and applicant a written statement that: (i) specifies the impact, *i.e.*, amount or extent, of such anticipated incidental take of the species that does not violate section 7(a)(2), (ii) specifies those reasonable and prudent measures necessary or appropriate to minimize such impact, (iii) sets forth the terms and conditions, including, but not limited to, reporting requirements, that must be complied with by the Federal agency or any applicant in order to implement the reasonable and prudent measures specified under (ii) above, and (iv) specifies the procedures to be used to handle or dispose of any individuals of a species actually taken. Several comments were received on these elements of the incidental take statement.

Because, in some cases, exact numerical limits on the amount of permissible incidental taking will be difficult to determine, the Service may, in accordance with (i)(1)(i), specify the extent of anticipated take that will not violate section 7(a)(2) of the Act. The impact of a particular action may only

be predictable in terms of the extent of land or marine area that may be affected. Precise numbers of individuals that may be taken are preferable to descriptions of the extent of disruption and will be provided when they can be computed. However, the Service reserves the flexibility in the rule so that the most appropriate standard for an individual consultation can be used. The Service declines to endorse the use of numerical amounts in all cases over the use of descriptions of extent, because for some species loss of habitat resulting in death or injury to individuals may be more deleterious than the direct loss of a certain number of individuals. Likewise, the Service declines to incorporate into the final rule the comment that would focus take levels on population numbers and recovery plan guidelines, if available. One commenter suggested that two figures or levels be specified: "the expected and the acceptable amount or extent" of take. This approach offers the benefit of giving a "caution" signal to Federal agencies or applicants as they approach a possible problem with the incidental takings resulting from the action. Steps could be taken to correct the course of the action before the threshold of reinitiation (level of maximum anticipated take) is exceeded. The Service recognizes the merit of this approach but does not require that it be followed under the final rule because it may not be appropriate for all Federal actions.

Paragraph (i)(1)(ii) states that the incidental take statement shall specify those reasonable and prudent measures necessary to minimize the level of incidental take. For the reasons discussed under the definition of reasonable and prudent measures, the Service has added a new paragraph (i)(2) to the final rule to clarify that reasonable and prudent measures may only involve minor changes that do not alter the basic design, location, duration, or timing of the action. Should the Service believe that the way to minimize the incidental takings is through research, an explanation of how such research will accomplish this will be included. Any research-related reasonable and prudent measure shall be subject to the limitations in paragraph (i)(2).

Paragraph (i)(1)(iii) provides that reporting requirements must be included in the terms and conditions of an incidental take statement. As explained in paragraph (i)(3), these reporting requirements will be tailored to the nature of the particular Federal action and will, to the extent possible, be

limited to existing reporting requirements.

Under 50 CFR 13.45 (FWS) and 222.23(d) (NMFS), there are provisions concerning reporting requirements for any taking of threatened or endangered species. These reporting requirements are not limited to annual reports, and may vary in accordance with the particular needs of the species as set forth in the incidental take statement. Congress did not prohibit the imposition of new reporting requirements, contrary to the assertion of one commenter.

Another commenter said that the disposal procedures in item (i)(1)(iv) should refer to "specimens" taken, not to species taken. The Service has accommodated the commenter's concern by inserting "individuals of a species" in item (iv).

Paragraph (i)(4) requires the Federal agency or the applicant to immediately request reinitiation of formal consultation if the specified amount or extent of incidental take is exceeded. One commenter argued that the Service is allowing the "jeopardy" ceiling to be exceeded in (i)(4). The Service disagrees; however, the Service agrees that the amount or extent of take should not be set at the threshold of likely jeopardy. If the establishment of such a high taking level were necessary to cover all impacts of a proposed action, it is questionable whether the issuance of a "no jeopardy" opinion is appropriate. It is not expected that the level of incidental take anticipated for most "no jeopardy" actions would come close to the section 7(a)(2) barrier.

Congress recognized this in the House Report to the 1982 Amendments:

If the specified impact on the species is exceeded, the Committee expects that the Federal agency or permittee or licensee will immediately reinitiate consultation since the level of taking exceeds the impact specified in the initial section 7(b)(4) statement. In the interim period between the initiation and completion of the new consultation, the Committee would not expect the Federal agency or permittee or licensee to cease all operations unless it was clear that the impact of the additional taking would cause an irreversible and adverse impact on the species.

H.R. Rep. No. 567, 97th Cong., 2d Sess. 27 (1982). Exceeding the level of anticipated taking does not, by itself, require the stopping of an ongoing action during reinitiation of consultation. The Federal agency must make this ultimate decision, taking into consideration the prohibitions of sections 7(a)(2) and 7(d). Further, the Service will enforce the taking prohibitions of section 4(d) or 9 if the continuation of an action, after the

anticipated level of incidental take has been reached, results in additional takings of listed species.

This provision for incidental take in no way affects a Federal agency's responsibility under section 7(a)(2) to ensure that its action is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat. The Service agrees with one commenter that the basis for the conclusion that incidental take will not violate section 7(a)(2) should be included with the biological opinion.

Paragraph (j) specifies that the Service may provide any conservation recommendations with the biological opinion. Several commenters objected to the inclusion of conservation recommendations in the biological opinion, and questioned whether these recommendations were to have binding force. The comment submitted by the House Committee summarized these concerns:

While the proposed regulations conform to the statute regarding the recommending of "reasonable and prudent alternatives" only where jeopardy is found, they also inject a totally new concept referred to as "conservation recommendations." Although we do not argue with the appropriateness of wildlife agencies recommending measures that could be taken to lessen a project's impact on endangered or threatened species, it should be made clear in the regulations that failure to abide by these recommendations does not result in a violation of section 7(a)(2) of the Act. In addition, while the language of section 7(a)(1) does direct all Federal agencies to "utilize their authorities in furtherance of the purposes of [the Act] by carrying out programs for the conservation of endangered species and threatened species", we do not believe that it was intended that section 7(a)(1) require developmental agency actions to be treated as conservation programs for endangered or threatened species. We also do not believe that all of the conservation recommendations of the Secretary have to be followed for this requirement to be met. Such an interpretation would render the much debated provisions of section 7(a)(2) redundant and essentially meaningless and bring about endless litigation.

Accordingly, we suggest that any conservation recommendations be transmitted to action agencies separate from biological opinions and that the regulations state plainly that failure to accept or implement the recommendations does not constitute a violation of section 7 of the Act.

The Service agrees with the Committee's comments and has amended the proposed rule accordingly. Discretionary conservation recommendations will be provided with the biological opinion as a separate statement rather than as an integral part

of the opinion. In this rule, conservation recommendations [402.14(j)] are discussed separately from biological opinions [402.14(h)]. A sentence has been added at the conclusion of paragraph (j) to emphasize the advisory, non-binding nature of conservation recommendations.

Paragraph (k) of § 402.14, which deals with incremental steps, is adopted with minor, technical changes from proposed § 402.15(j)(2). Paragraph (k) applies, at the option of the Federal agency, in situations where a statute authorizes the Federal action to be taken in incremental steps. Such circumstances existed in *North Slope Borough v. Andrus*, 642 F.2d 589 (D.C. Cir. 1980), involving development of oil and gas resources on the OCS and possible impacts to the bowhead whale. In view of this decision, these regulations provide that a Federal agency may proceed with incremental steps toward completion of the entire action if: (1) the biological opinion does not conclude that the incremental step would violate section 7(a)(2); (2) the Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step; (3) the Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action; (4) the incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and (5) there is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

In response to one comment, the Service acknowledges that the incremental step process can only be invoked at the option of the Federal agency, regardless of the Service's preference. If the Federal agency chooses not to use the incremental step process, the Service must render its biological opinion for the entire action.

Several commenters thought that this provision should be deleted. Some thought the subject should be handled through counterpart regulations or limited strictly to Outer Continental Shelf Lands Act cases. Another commenter stated that the incremental step approach is ill-advised because it is difficult to halt a project at its final stage after substantial resources have been invested. Finally, two commenters criticized the approach as a vehicle granting the Service veto power at any stage of the Federal action.

Paragraph (k) is retained in the final rule for several reasons. First, the Service adopts paragraph (k) because it provides a viable consultation approach

sanctioned by the court in *North Slope Borough v. Andrus*, *supra*. The Service has clarified the final rule to show that it will not deprive a Federal agency of the opportunity to consult on incremental steps if requested. Second, the risk of section 7(a)(2) and 7(d) noncompliance should not be diminished because the incremental step approach is used. Monetary investments or other actions that do not foreclose the adoption of reasonable and prudent alternatives do not violate section 7(d). If a "jeopardy" opinion is issued at any step of the overall action, a prompt remedy can be sought through the exemption procedure. Third, consulting in incremental steps can be a valuable tool for developing information as an action progresses.

Oil and gas development on the OCS is a multistaged, long term action that provides a good example of the utility of an incremental step consultation. The Federal action occurs in discrete stages: the lease sale, exploration activities, and development/production activities. Any analysis of the impacts of development/production would be mere speculation without knowing what tracts will be leased and without the information on the extent of the petroleum reserves discovered during the exploration phase. As the scope and location of the ultimate action is further refined, the Federal agency will have the opportunity to conduct studies designed to determine the effects of that particular action in that particular area.

The Service is sympathetic to the commenter's concern that applicants might face an arduous series of consultations under paragraph (k), whereas a prompt consultation on the entire action would avoid a series of reviews by the Service. The Service reminds applicants that they may, in appropriate instances, avail themselves of the early consultation procedure to obtain a preapplication review of the remaining steps of the Federal action.

Under paragraph (k), biological opinions concluding "no jeopardy," or Service concurrence letters finding that a step "is not likely to adversely affect," must eventually cover each step of the incremental process. This does not mean that separate opinions must be issued for each step—several steps may be covered in one opinion (e.g., OCS leasing and exploration activities)—but instead that each step must eventually satisfy section 7(a)(2) of the Act. A "jeopardy" opinion issued at any stage not only applies to that step but to the entire project as well. Once a "jeopardy" opinion is issued (unless the Federal agency adopts a reasonable and prudent alternative provided by the

Service), paragraph (k) is inapplicable and the ordinary consultation process applies, allowing access to the exemption process. The commenter that contended that this approach is tantamount to a usurpation of Federal agency statutory authority ignores the fact that this process is at the option of the Federal agency and that the net effect of the Service's action is to cause the consultation to revert to a treatment of the action as a whole. The Federal agency may disagree with the Service's "jeopardy" finding, but it cannot continue to consult on an incremental basis on remaining steps in the action.

One commenter insisted that an action can be halted only if new information that was not previously known becomes available during a later stage of the incremental step consultation. However, the Service's responsibility to determine "jeopardy" or "no jeopardy" places no weight on when, where, or how data that is of compelling force in its analysis were developed. The Service cannot ignore data and permit a listed species to become jeopardized because someone "missed" a piece of information during an earlier step of the consultation. One of the criteria for reinitiation of formal consultation is whether new information reveals effects of the action that may affect a listed species or critical habitat in a manner or to an extent not previously considered. Therefore, incremental step consultations are not the only consultations subjected to this requirement.

Finally, one commenter objected to the requirement for obtaining sufficient data, noting an alleged absence of statutory authority. Again, paragraph (k) is not a creature of statute, but instead was developed so that consultations could be initiated and focused on a step-by-step review of segmented Federal actions—especially those where, in the absence of additional information, the final determination of "likely jeopardy" for the entire action would be highly speculative if consultation were not limited to the initial step or steps. The development of sufficient information is crucial to the ultimate success of the incremental step process, and, therefore, cannot be eliminated from the rule. The Federal agency must have sufficient information to show that its action is not likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

Section 402.14(l) covers the termination of formal consultation. Adopted from proposed § 402.15(i)(2)–(4), paragraph (l) was retained in the section

on formal consultation because §402.14 is the primary mandatory procedure of Part 402.

The proposed rule provided that consultation terminated with the issuance of a "no jeopardy" opinion unless further discussion took place, and, if a "jeopardy" opinion was issued, consultation terminated with the Service's receipt of the Federal agency's decision on the action. This notice requirement was criticized by several commenters as unnecessary and as extending consultation beyond the legal timeframe. As discussed under the "Definitions" section above, further discussion has been deleted as a formal step in the consultation process. Further, to accommodate the concerns, consultation terminates with the issuance of the biological opinion, whether "jeopardy" or "no jeopardy." However, the Service believes that the Federal agency notice of final action with respect to "jeopardy" opinions represents a minimal burden and has retained it under §402.15—

"Responsibilities of Federal agency following issuance of a biological opinion." The Service agrees that a copy of the NEPA record of decision would meet the notice provisions of §402.15(b); the Service disagrees that this approach causes problems with NEPA compliance.

Finally, one commenter suggested that written notice be required to terminate consultation if a Federal agency or applicant decides to cancel plans for the action that is the subject of the consultation. The Service agrees that a written notice of termination is preferred, and has adopted the commenter's suggestion in paragraph (l)(2).

Section 402.15 Responsibilities of Federal Agency Following Issuance of a Biological Opinion.

Following the receipt of the Service's biological opinion, the Federal agency will make its final decision on the action. Section 402.15 describes the steps that the Federal agency should take after consultation is concluded. Paragraphs (a) and (c) of this section are adopted substantially without change from proposed §402.17. Paragraph (b) is adopted from proposed §402.15(i)(3) (last sentence).

Several commenters asked that the Federal agency be required to provide a statement of its reasons if it has chosen to disregard the Service's biological opinion. The Service declines to implement this request, because it remains the responsibility of each Federal agency to insure that it is in compliance with section 7(a)(2) and that

it has established an administrative record for a given activity which demonstrates such compliance.

Federal courts have accorded Service biological opinions great deference. It, therefore, is incumbent upon a Federal agency to articulate in its administrative record its reasons for disagreeing with the conclusions of a biological opinion. But this is a matter which is primarily controlled under the provisions and judicial interpretations of the Administrative Procedure Act, not these regulations. Thus, the requested modification would add nothing that is not already required as a matter of administrative law.

Paragraph (c) points out the availability of an exemption process if the Federal agency determines that its proposed action cannot comply with section 7(a)(2). Although not covered in §402.15, the applicant may also pursue an exemption if it receives a final denial of its application as a result of a "jeopardy" biological opinion. The Service disagrees with one commenter that the applicant may seek an exemption if the Federal agency issues the permit or license with conditions related to section 7 considerations. The Act requires a final agency denial, and the issuance of a "jeopardy" biological opinion on the action, as predicates for an applicant's entry into the exemption process. See sections 3(12) and 7(g)(1) of the Act.

Section 402.16 Reinitiation of Formal Consultation.

Reinitiation of formal consultation is required in certain instances as specified in §402.16. The reinitiation requirement applies only to actions that remain subject to some Federal involvement or control. In the case where a permit or license had been granted, reinitiation would not be appropriate unless the permitting or licensing agency retained jurisdiction over the matter under the terms of the permit or license or as otherwise authorized by law.

In response to one comment, the Service notes its lack of authority to require Federal agencies to reinitiate consultation if they choose not to do so. Nevertheless, the Service shall request reinitiation when it believes that any condition described in this section applies.

Pursuant to several public comments, several minor changes have been made to §402.16 (proposed §402.18). Proposed paragraph (a), dealing with nonconfirmation of preliminary biological opinions, was deleted since it is more properly covered in the discussion of early consultation. The

standard for reinitiation on incidental take statements is clarified in new paragraph (a). Paragraph (c) is clarified to show that changes to the action that do not cause effects different from or additional to those considered in the biological opinion will not require reinitiation of formal consultation.

Summary

The Amendments made significant changes in the consultation requirements of section 7, and the Service believes that a consistent response by the Federal agencies to those Amendments, as implemented by this final rule, will facilitate successful compliance with section 7 of the Act. The Service believes that these regulations will serve as an effective tool for the early resolution of potential conflicts involving listed species.

The primary authors of this final rule are Michael Young and Nancy Sweeney, Department of the Interior; Patricia Carter, Patricia Montanio, and Michael Gosliner, Department of Commerce.

The Department of the Interior, as lead agency in the development of these regulations, has prepared an environmental assessment in conjunction with this rulemaking. On the basis of the environmental assessment, it has been determined that this is not a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act of 1969 (implemented at 40 CFR Parts 1500–1508). Therefore, an environmental impact statement need not be prepared. These procedural regulations simply provide a uniform approach for consultation required by section 7 of the Act. Compliance with the procedures in these regulations will not have any significant, direct, or indirect adverse environmental impact. It also has been determined that these regulations do not constitute major rules as defined in Executive Order 12291. The Department of the Interior has certified, under the terms of the Regulatory Flexibility Act (5 U.S.C. 601), that these regulations will not have a significant economic impact on a substantial number of small entities. The regulations are directed at Federal actions. The costs to small entities are those involved with timing and data gathering, if requested by the Federal agency. Even if the costs were passed on, the analysis under the Regulatory Flexibility Act has concluded that they are not substantial. The Department has determined that these rules do not contain "collection of information" or recordkeeping

requirements as defined by the Paperwork Reduction Act. The analyses under Executive Order 12291, the Regulatory Flexibility Act, and NEPA are available to the public at the Office of Endangered Species, U.S. Fish and Wildlife Service, at the address listed above.

List of Subjects in 50 CFR Part 402

Endangered and threatened wildlife, Fish, Intergovernmental relations, Plants (agriculture).

Regulation Promulgation

Accordingly, the Service revises 50 CFR Part 402 to read as follows:

PART 402—INTERAGENCY COOPERATION—ENDANGERED SPECIES ACT OF 1973, AS AMENDED

Subpart A—General

- Sec.
- 402.01 Scope.
 - 402.02 Definitions.
 - 402.03 Applicability.
 - 402.04 Counterpart regulations.
 - 402.05 Emergencies.
 - 402.06 Coordination with other environmental reviews.
 - 402.07 Designation of lead agency.
 - 402.08 Designation of non-Federal representative.
 - 402.09 Irreversible or irretrievable commitment of resources.

Subpart B—Consultation Procedures

- 402.10 Conference on proposed species or proposed critical habitat.
- 402.11 Early consultation.
- 402.12 Biological assessment.
- 402.13 Informal consultation.
- 402.14 Formal consultation.
- 402.15 Responsibilities of Federal agency following issuance of a biological opinion.
- 402.16 Reinitiation of formal consultation.

Authority: 16 U.S.C. 1531 *et seq.*

Subpart A—General

§ 402.01 Scope.

(a) This Part interprets and implements sections 7(a)–(d) [16 U.S.C. 1536(a)–(d)] of the Endangered Species Act of 1973, as amended ("Act"). Section 7(a) grants authority to and imposes requirements upon Federal agencies regarding endangered or threatened species of fish, wildlife, or plants ("listed species") and habitat of such species that has been designated as critical ("critical habitat"). Section 7(a)(1) of the Act directs Federal agencies, in consultation with and with the assistance of the Secretary of the Interior or of Commerce, as appropriate, to utilize their authorities to further the purposes of the Act by carrying out conservation programs for listed species. Such affirmative conservation

programs must comply with applicable permit requirements (50 CFR Parts 17, 220, 222, and 227) for listed species and should be coordinated with the appropriate Secretary. Section 7(a)(2) of the Act requires every Federal agency, in consultation with and with the assistance of the Secretary, to insure that any action it authorizes, funds, or carries out, in the United States or upon the high seas, is not likely to jeopardize the continued existence of any listed species or results in the destruction or adverse modification of critical habitat. Section 7(a)(3) of the Act authorizes a prospective permit or license applicant to request the issuing Federal agency to enter into early consultation with the Service on a proposed action to determine whether such action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat. Section 7(a)(4) of the Act requires Federal agencies to confer with the Secretary on any action that is likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat. Section 7(b) of the Act requires the Secretary, after the conclusion of early or formal consultation, to issue a written statement setting forth the Secretary's opinion detailing how the agency action affects listed species or critical habitat. Biological assessments are required under section 7(c) of the Act if listed species or critical habitat may be present in the area affected by any major construction activity as defined in § 404.02. Section 7(d) of the Act prohibits Federal agencies and applicants from making any irreversible or irretrievable commitment of resources which has the effect of foreclosing the formulation or implementation of reasonable and prudent alternatives which would avoid jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat. Section 7(e)–(o)(1) of the Act provide procedures for granting exemptions from the requirements of section 7(a)(2). Regulations governing the submission of exemption applications are found at 50 CFR Part 451, and regulations governing the exemption process are found at 50 CFR Parts 450, 452, and 453.

(b) The U.S. Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) share responsibilities for administering the Act. The Lists of Endangered and Threatened Wildlife and Plants are found in 50 CFR 17.11 and 17.12 and the designated critical habitats are found in 50 CFR 17.95 and 17.96 and 50 CFR Part

226. Endangered or threatened species under the jurisdiction of the NMFS are located in 50 CFR 222.23(a) and 227.4. If the subject species is cited in 50 CFR 222.23(a) or 227.4, the Federal agency shall contact the NMFS. For all other listed species the Federal Agency shall contact the FWS.

§ 402.02 Definitions.

"Act" means the Endangered Species Act of 1973, as amended, 16 U.S.C. 1531 *et seq.*

"Action" means all activities or programs of any kind authorized, funded, or carried out, in whole or in part, by Federal agencies in the United States or upon the high seas. Examples include, but are not limited to: (a) actions intended to conserve listed species or their habitat; (b) the promulgation of regulations; (c) the granting of licenses, contracts, leases, easements, rights-of-way, permits, or grants-in-aid; or (d) actions directly or indirectly causing modifications to the land, water, or air.

"Action area" means all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action.

"Applicant" refers to any person, as defined in section 3(13) of the Act, who requires formal approval or authorization from a Federal agency as a prerequisite to conducting the action.

"Biological assessment" refers to the information prepared by or under the direction of the Federal agency concerning listed and proposed species and designated and proposed critical habitat that may be present in the action area and the evaluation potential effects of the action on such species and habitat.

"Biological opinion" is the document that states the opinion of the Service as to whether or not the Federal action is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

"Conference" is a process which involves informal discussions between a Federal agency and the Service under section 7(a)(4) of the Act regarding the impact of an action on proposed species or proposed critical habitat and recommendations to minimize or avoid the adverse effects.

"Conservation recommendations" are suggestions of the Service regarding discretionary measures to minimize or avoid adverse effects of a proposed action on listed species or critical habitat or regarding the development of information.

"Critical habitat" refers to an area designated as critical habitat listed in 50 CFR Parts 17 or 226.

"Cumulative effects" are those effects of future State or private activities, not involving Federal activities, that are reasonably certain to occur within the action area of the Federal action subject to consultation.

"Designated non-Federal representative" refers to a person designated by the Federal agency as its representative to conduct informal consultation and/or to prepare any biological assessment.

"Destruction or adverse modification" means a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to, alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.

"Director" refers to the Assistant Administrator for Fisheries for the National Oceanic and Atmospheric Administration, or his authorized representative; or the Fish and Wildlife Service regional director, or his authorized representative, for the region where the action would be carried out.

"Early consultation" is a process requested by a Federal agency on behalf of a prospective applicant under section 7(a)(3) of the Act.

"Effects of the action" refers to the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action, that will be added to the environmental baseline. The environmental baseline includes the past and present impacts of all Federal, State, or private actions and other human activities in the action area, the anticipated impacts of all proposed Federal projects in the action area that have already undergone formal or early section 7 consultation, and the impact of State or private actions which are contemporaneous with the consultation in process. Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. Interdependent actions are those that have no independent utility apart from the action under consideration.

"Formal consultation" is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and

concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.

"Incidental take" refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant.

"Informal consultation" is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative prior to formal consultation, if required.

"Jeopardize the continued existence of" means to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species.

"Listed species" means any species of fish, wildlife, or plant which has been determined to be endangered or threatened under section 4 of the Act. Listed species are found in 50 CFR 17.11-17.12.

"Major construction activity" is a construction project (or other undertaking having similar physical impacts) which is a major Federal action significantly affecting the quality of the human environment as referred to in the National Environmental Policy Act [NEPA, 42 U.S.C. 4332(2)(C)].

"Preliminary biological opinion" refers to an opinion issued as a result of early consultation.

"Proposed critical habitat" means habitat proposed in the *Federal Register* to be designated or revised as critical habitat under section 4 of the Act for any listed or proposed species.

"Proposed species" means any species of fish, wildlife, or plant that is proposed in the *Federal Register* to be listed under section 4 of the Act.

"Reasonable and prudent alternatives" refer to alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction, that is economically and technologically feasible, and that the Director believes would avoid the likelihood of jeopardizing the continued existence of listed species or resulting in the destruction or adverse modification of critical habitat.

"Reasonable and prudent measures" refer to those actions the Director believes necessary or appropriate to minimize the impacts, *i.e.*, amount or extent, of incidental take.

"Recovery" means improvement in the status of listed species to the point at which listing is no longer appropriate under the criteria set out in section 4(a)(1) of the Act.

"Service" means the U.S. Fish and Wildlife Service or the National Marine Fisheries Service, as appropriate.

§402.03 Applicability.

Section 7 and the requirements of this Part apply to all actions in which there is discretionary Federal involvement or control.

§402.04 Counterpart regulations.

The consultation procedures set forth in this Part may be superseded for a particular Federal agency by joint counterpart regulations among that agency, the Fish and Wildlife Service, and the National Marine Fisheries Service. Such counterpart regulations shall be published in the *Federal Register* in proposed form and shall be subject to public comment for at least 60 days before final rules are published.

§402.05 Emergencies.

(a) Where emergency circumstances mandate the need to consult in an expedited manner, consultation may be conducted informally through alternative procedures that the Director determines to be consistent with the requirements of sections 7(a)-(d) of the Act. This provision applies to situations involving acts of God, disasters, casualties, national defense or security emergencies, etc.

(b) Formal consultation shall be initiated as soon as practicable after the emergency is under control. The Federal agency shall submit information on the nature of the emergency action(s), the justification for the expedited consultation, and the impacts to endangered or threatened species and their habitats. The Service will evaluate such information and issue a biological opinion including the information and recommendations given during the emergency consultation.

§402.06 Coordination with other environmental reviews.

(a) Consultation, conference, and biological assessment procedures under section 7 may be consolidated with interagency cooperation procedures required by other statutes, such as the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*, implemented at 40 CFR Parts 1500-1508) or the Fish and Wildlife Coordination Act (FWCA) (16 U.S.C. 661 *et seq.*). Satisfying the requirements of these other statutes, however, does not in itself relieve a Federal agency of its

obligations to comply with the procedures set forth in this Part or the substantive requirements of section 7. The Service will attempt to provide a coordinated review and analysis of all environmental requirements.

(b) Where the consultation or conference has been consolidated with the interagency cooperation procedures required by other statutes such as NEPA or FWCA, the results should be included in the documents required by those statutes.

§402.07 Designation of lead agency.

When a particular action involves more than one Federal agency, the consultation and conference responsibilities may be fulfilled through a lead agency. Factors relevant in determining an appropriate lead agency include the time sequence in which the agencies would become involved, the magnitude of their respective involvement, and their relative expertise with respect to the environmental effects of the action. The Director shall be notified of the designation in writing by the lead agency.

§402.08 Designation of non-Federal representative.

A Federal agency may designate a non-Federal representative to conduct informal consultation or prepare a biological assessment by giving written notice to the Director of such designation. If a permit or license applicant is involved and is not the designated non-Federal representative, then the applicant and Federal agency must agree on the choice of the designated non-Federal representative. If a biological assessment is prepared by the designated non-Federal representative, the Federal agency shall furnish guidance and supervision and shall independently review and evaluate the scope and contents of the biological assessment. The ultimate responsibility for compliance with section 7 remains with the Federal agency.

§402.09 Irreversible or Irrecoverable commitment of resources.

After initiation or reinitiation of consultation required under section 7(a)(2) of the Act, the Federal agency and any applicant shall make no irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternatives which would avoid violating section 7(a)(2). This prohibition is in force during the consultation process and continues until the requirements of section 7(a)(2) are

satisfied. This provision does not apply to the conference requirement for proposed species or proposed critical habitat under section 7(a)(4) of the Act.

Subpart B—Consultation Procedures

§ 402.10 Conference on proposed species or proposed critical habitat.

(a) Each Federal agency shall confer with the Service on any action which is likely to jeopardize the continued existence of any proposed species or result in the destruction or adverse modification of proposed critical habitat. The conference is designed to assist the Federal agency and any applicant in identifying and resolving potential conflicts at an early stage in the planning process.

(b) The Federal agency shall initiate the conference with the Director. The Service may request a conference if, after a review of available information, it determines that a conference is required for a particular action.

(c) A conference between a Federal agency and the Service shall consist of informal discussions concerning an action that is likely to jeopardize the continued existence of the proposed species or result in the destruction or adverse modification of the proposed critical habitat at issue. Applicants may be involved in these informal discussions to the greatest extent practicable. During the conference, the Service will make advisory recommendations, if any, on ways to minimize or avoid adverse effects. If the proposed species is subsequently listed or the proposed critical habitat is designated prior to completion of the action, the Federal agency must review the action to determine whether formal consultation is required.

(d) If requested by the Federal agency and deemed appropriate by the Service, the conference may be conducted in accordance with the procedures for formal consultation in § 402.14. An opinion issued at the conclusion of the conference may be adopted as the biological opinion when the species is listed or critical habitat is designated, but only if no significant new information is developed (including that developed during the rulemaking process on the proposed listing or critical habitat designation) and no significant changes to the Federal action are made that would alter the content of the opinion. An incidental take statement provided with a conference opinion does not become effective unless the Service adopts the opinion once the listing is final.

(e) The conclusions reached during a conference and any recommendations

shall be documented by the Service and provided to the Federal agency and to any applicant. The style and magnitude of this document will vary with the complexity of the conference. If formal consultation also is required for a particular action, then the Service will provide the results of the conference with the biological opinion.

§ 402.11 Early consultation.

(a) *Purpose.* Early consultation is designed to reduce the likelihood of conflicts between listed species or critical habitat and proposed actions and occurs prior to the filing of an application for a Federal permit or license. Although early consultation is conducted between the Service and the Federal agency, the prospective applicant should be involved throughout the consultation process.

(b) *Request by prospective applicant.* If a prospective applicant has reason to believe that the prospective action may affect listed species or critical habitat, it may request the Federal agency to enter into early consultation with the Service. The prospective applicant must certify in writing to the Federal agency that (1) it has a definitive proposal outlining the action and its effects and (2) it intends to implement its proposal, if authorized.

(c) *Initiation of early consultation.* If the Federal agency receives the prospective applicant's certification in paragraph (b) of this section, then the Federal agency shall initiate early consultation with the Service. This request shall be in writing and contain the information outlined in § 402.14(c) and, if the action is a major construction activity, the biological assessment as outlined in § 402.12.

(d) *Procedures and responsibilities.* The procedures and responsibilities for early consultation are the same as outlined in § 402.14(c)-(j) for formal consultation, except that all references to the "applicant" shall be treated as the "prospective applicant" and all references to the "biological opinion" or the "opinion" shall be treated as the "preliminary biological opinion" for the purpose of this section.

(e) *Preliminary biological opinion.* The contents and conclusions of a preliminary biological opinion are the same as for a biological opinion issued after formal consultation except that the incidental take statement provided with a preliminary biological opinion does not constitute authority to take listed species.

(f) *Confirmation of preliminary biological opinion as final biological opinion.* A preliminary biological opinion may be confirmed as a

biological opinion issued after formal consultation if the Service reviews the proposed action and finds that there have been no significant changes in the action as planned or in the information used during the early consultation. A written request for confirmation of the preliminary biological opinion should be submitted after the prospective applicant applies to the Federal agency for a permit or license but prior to the issuance of such permit or license. Within 45 days of receipt of the Federal agency's request, the Service shall either: (1) confirm that the preliminary biological opinion stands as a final biological opinion; or (2) if the findings noted above cannot be made, request that the Federal agency initiate formal consultation.

§402.12 Biological assessments.

(a) *Purpose.* A biological assessment shall evaluate the potential effects of the action on listed and proposed species and designated and proposed critical habitat and determine whether any such species or habitat are likely to be adversely affected by the action and is used in determining whether formal consultation or a conference is necessary.

(b) *Preparation requirement.* (1) The procedures of this section are required for Federal actions that are "major construction activities"; provided that a contract for construction was not entered into or actual construction was not begun on or before November 10, 1978. Any person, including those who may wish to apply for an exemption from section 7(a)(2) of the Act, may prepare a biological assessment under the supervision of the Federal agency and in cooperation with the Service consistent with the procedures and requirements of this section. An exemption from the requirements of section 7(a)(2) is not permanent unless a biological assessment has been prepared.

(2) The biological assessment shall be completed before any contract for construction is entered into and before construction is begun.

(c) *Request for information.* The Federal agency or the designated non-Federal representative shall convey to the Director either (1) a written request for a list of any listed or proposed species or designated or proposed critical habitat that may be present in the action area; or (2) a written notification of the species and critical habitat that are being included in the biological assessment.

(d) *Director's response.* Within 30 days of receipt of the notification of, or the request for, a species list, the

Director shall either concur with or revise the list or, in those cases where no list has been provided, advise the Federal agency or the designated non-Federal representative in writing whether, based on the best scientific and commercial data available, any listed or proposed species or designated or proposed critical habitat may be present in the action area. In addition to listed and proposed species, the Director will provide a list of candidate species that may be present in the action area. Candidate species refers to any species being considered by the Service for listing as endangered or threatened species but not yet the subject of a proposed rule. Although candidate species have no legal status and are accorded no protection under the Act, their inclusion will alert the Federal agency of potential proposals or listings.

(1) If the Director advises that no listed species or critical habitat may be present, the Federal agency need not prepare a biological assessment and further consultation is not required. If only proposed species or proposed critical habitat may be present in the action area, then the Federal agency must confer with the Service if required under §402.10, but preparation of a biological assessment is not required unless the proposed listing and/or designation becomes final.

(2) If a listed species or critical habitat may be present in the action area, the Director will provide a species list or concur with the species list provided. The Director also will provide available information (or references thereto) regarding these species and critical habitat, and may recommend discretionary studies or surveys that may provide a better information base for the preparation of an assessment. Any recommendation for studies or surveys is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act.

(e) *Verification of current accuracy of species list.* If the Federal agency or the designated non-Federal representative does not begin preparation of the biological assessment within 90 days of receipt of (or concurrence with) the species list, the Federal agency or the designated non-Federal representative must verify (formally or informally) with the Service the current accuracy of the species list at the time the preparation of the assessment is begun.

(f) *Contents.* The contents of a biological assessment are at the discretion of the Federal agency and will depend on the nature of the Federal

action. The following may be considered for inclusion:

(1) The results of an on-site inspection of the area affected by the action to determine if listed or proposed species are present or occur seasonally.

(2) The views of recognized experts on the species at issue.

(3) A review of the literature and other information.

(4) An analysis of the effects of the action on the species and habitat, including consideration of cumulative effects, and the results of any related studies.

(5) An analysis of alternate actions considered by the Federal agency for the proposed action.

(g) *Incorporation by reference.* If a proposed action requiring the preparation of a biological assessment is identical, or very similar, to a previous action for which a biological assessment was prepared, the Federal agency may fulfill the biological assessment requirement for the proposed action by incorporating by reference the earlier biological assessment, plus any supporting data from other documents that are pertinent to the consultation, into a written certification that:

(1) The proposed action involves similar impacts to the same species in the same geographic area;

(2) No new species have been listed or proposed or no new critical habitat designated or proposed for the action area; and

(3) The biological assessment has been supplemented with any relevant changes in information.

(h) *Permit requirements.* If conducting a biological assessment will involve the taking of a listed species, a permit under section 10 of the Act (16 U.S.C. 1539) and Part 17 of this Title (with respect to species under the jurisdiction of the FWS) or Parts 220, 222, and 227 of this Title (with respect to species under the jurisdiction of the NMFS) is required.

(i) *Completion time.* The Federal agency or the designated non-Federal representative shall complete the biological assessment within 180 days after its initiation (receipt of or concurrence with the species list) unless a different period of time is agreed to by the Director and the Federal agency. If a permit or license applicant is involved, the 180-day period may not be extended unless the agency provides the applicant, before the close of the 180-day period, with a written statement setting forth the estimated length of the proposed extension and the reasons why such an extension is necessary.

(j) *Submission of biological assessment.* The Federal agency shall

submit the completed biological assessment to the Director for review. The Director will respond in writing within 30 days as to whether or not he concurs with the findings of the biological assessment. At the option of the Federal agency, formal consultation may be initiated under § 402.14(c) concurrently with the submission of the assessment.

(k) Use of the biological assessment.

(1) The Federal agency shall use the biological assessment in determining whether formal consultation or a conference is required under § 402.14 or § 402.10, respectively. If the biological assessment indicates that there are no listed species or critical habitat present that are likely to be adversely affected by the action and the Director concurs as specified in paragraph (j) of this section, then formal consultation is not required. If the biological assessment indicates that the action is not likely to jeopardize the continued existence of proposed species or result in the destruction or adverse modification of proposed critical habitat, and the Director concurs, then a conference is not required.

(2) The Director may use the results of the biological assessment in (i) determining whether to request the Federal agency to initiate formal consultation or a conference, (ii) formulating a biological opinion, or (iii) formulating a preliminary biological opinion.

§ 402.13 Informal consultation.

(a) Informal consultation is an optional process that includes all discussions, correspondence, etc., between the Service and the Federal agency or the designated non-Federal representative, designed to assist the Federal agency in determining whether formal consultation or a conference is required. If during informal consultation it is determined by the Federal agency, with the written concurrence of the Service, that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary.

(b) During informal consultation, the Service may suggest modifications to the action that the Federal agency and any applicant could implement to avoid the likelihood of adverse effects to listed species or critical habitat.

§ 402.14 Formal consultation.

(a) *Requirement for formal consultation.* Each Federal agency shall review its actions at the earliest possible time to determine whether any action may affect listed species or

critical habitat. If such a determination is made, formal consultation is required, except as noted in paragraph (b) of this section. The Director may request a Federal agency to enter into consultation if he identifies any action of that agency that may affect listed species or critical habitat and for which there has been no consultation. When such a request is made, the Director shall forward to the Federal agency a written explanation of the basis for the request.

(b) *Exceptions.* (1) A Federal agency need not initiate formal consultation if, as a result of the preparation of a biological assessment under § 402.12 or as a result of informal consultation with the Service under § 402.13, the Federal agency determines, with the written concurrence of the Director, that the proposed action is not likely to adversely affect any listed species or critical habitat.

(2) A Federal agency need not initiate formal consultation if a preliminary biological opinion, issued after early consultation under § 402.11, is confirmed as the final biological opinion.

(c) *Initiation of formal consultation.* A written request to initiate formal consultation shall be submitted to the Director and shall include:

(1) A description of the action to be considered;

(2) A description of the specific area that may be affected by the action;

(3) A description of any listed species or critical habitat that may be affected by the action;

(4) A description of the manner in which the action may affect any listed species or critical habitat and an analysis of any cumulative effects;

(5) Relevant reports, including any environmental impact statement, environmental assessment, or biological assessment prepared; and

(6) Any other relevant available information on the action, the affected listed species, or critical habitat. Formal consultation shall not be initiated by the Federal agency until any required biological assessment has been completed and submitted to the Director in accordance with § 402.12. Any request for formal consultation may encompass, subject to the approval of the Director, a number of similar individual actions within a given geographical area or a segment of a comprehensive plan. This does not relieve the Federal agency of the requirements for considering the effects of the action as a whole.

(d) *Responsibility to provide best scientific and commercial data available.* The Federal agency requesting formal consultation shall

provide the Service with the best scientific and commercial data available or which can be obtained during the consultation for an adequate review of the effects that an action may have upon listed species or critical habitat. This information may include the results of studies or surveys conducted by the Federal agency or the designated non-Federal representative. The Federal agency shall provide any applicant with the opportunity to submit information for consideration during the consultation.

(e) *Duration and extension of formal consultation.* Formal consultation concludes within 90 days after its initiation unless extended as provided below. If an applicant is not involved, the Service and the Federal agency may mutually agree to extend the consultation for a specific time period. If an applicant is involved, the Service and the Federal agency may mutually agree to extend the consultation provided that the Service submits to the applicant, before the close of the 90 days, a written statement setting forth:

(1) The reasons why a longer period is required,

(2) The information that is required to complete the consultation, and

(3) The estimated date on which the consultation will be completed.

A consultation involving an applicant cannot be extended for more than 60 days without the consent of the applicant. Within 45 days after concluding formal consultation, the Service shall deliver a biological opinion to the Federal agency and any applicant.

(f) *Additional data.* When the Service determines that additional data would provide a better information base from which to formulate a biological opinion, the Director may request an extension of formal consultation and request that the Federal agency obtain additional data to determine how or to what extent the action may affect listed species or critical habitat. If formal consultation is extended by mutual agreement according to § 402.14(e), the Federal agency shall obtain, to the extent practicable, that data which can be developed within the scope of the extension. The responsibility for conducting and funding any studies belongs to the Federal agency and the applicant, not the Service. The Service's request for additional data is not to be construed as the Service's opinion that the Federal agency has failed to satisfy the information standard of section 7(a)(2) of the Act. If no extension of formal consultation is agreed to, the Director will issue a biological opinion

using the best scientific and commercial data available.

(g) *Service responsibilities.* Service responsibilities during formal consultation are as follows:

(1) Review all relevant information provided by the Federal agency or otherwise available. Such review may include an on-site inspection of the action area with representatives of the Federal agency and the applicant.

(2) Evaluate the current status of the listed species or critical habitat.

(3) Evaluate the effects of the action and cumulative effects on the listed species or critical habitat.

(4) Formulate its biological opinion as to whether the action, taken together with cumulative effects, is likely to jeopardize the continued existence of listed species or result in the destruction or adverse modification of critical habitat.

(5) Discuss with the Federal agency and any applicant the Service's review and evaluation conducted under paragraphs (g)(1)-(3) of this section, the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2). The Service will utilize the expertise of the Federal agency and any applicant in identifying these alternatives. If requested, the Service shall make available to the Federal agency the draft biological opinion for the purpose of analyzing the reasonable and prudent alternatives. The 45-day period in which the biological opinion must be delivered will not be suspended unless the Federal agency secures the written consent of the applicant to an extension to a specific date. The applicant may request a copy of the draft opinion from the Federal agency. All comments on the draft biological opinion must be submitted to the Service through the Federal agency, although the applicant may send a copy of its comments directly to the Service. The Service will not issue its biological opinion prior to the 45-day or extended deadline while the draft is under review by the Federal agency. However, if the Federal agency submits comments to the Service regarding the draft biological opinion within 10 days of the deadline for issuing the opinion, the Service is entitled to an automatic 10-day extension on the deadline.

(6) Formulate discretionary conservation recommendations, if any, which will assist the Federal agency in reducing or eliminating the impacts that its proposed action may have on listed species or critical habitat.

(7) Formulate a statement concerning incidental take, if such take may occur.

(8) In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best scientific and commercial data available and will give appropriate consideration to any beneficial actions taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation.

(h) *Biological opinions.* The biological opinion shall include:

(1) A summary of the information on which the opinion is based;

(2) A detailed discussion of the effects of the action on listed species or critical habitat; and

(3) The Service's opinion on whether the action is likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "jeopardy biological opinion"); or, the action is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat (a "no jeopardy" biological opinion). A "jeopardy" biological opinion shall include reasonable and prudent alternatives, if any. If the Service is unable to develop such alternatives, it will indicate that to the best of its knowledge there are no reasonable and prudent alternatives.

(i) *Incidental take.* (1) In those cases where the Service concludes that an action (or the implementation of any reasonable and prudent alternatives) and the resultant incidental take of listed species will not violate section 7(a)(2), the Service will provide with the biological opinion a statement concerning incidental take that:

(i) Specifies the impact, i.e., the amount or extent, of such incidental taking of the species;

(ii) Specifies those reasonable and prudent measures that the Director considers necessary or appropriate to minimize such impact;

(iii) Sets forth the terms and conditions (including, but not limited to, reporting requirements) that must be complied with by the Federal agency or any applicant to implement the measures specified under (ii) above; and

(iv) Specifies the procedures to be used to handle or dispose of any individuals of a species actually taken.

(2) Reasonable and prudent measures, along with the terms and conditions that implement them, cannot alter the basic design, location, scope, duration, or timing of the action and may involve only minor changes.

(3) In order to monitor the impacts of incidental take, the Federal agency or any applicant must report the progress of the action and its impact on the species to the Service as specified in the incidental take statement. The reporting requirements will be established in accordance with 50 CFR 13.45(FWS) and 222.23(d)(NMFS).

(4) If during the course of the action the amount or extent of incidental taking, as specified under paragraph (i)(1)(i) of this Section, is exceeded, the Federal agency must reinstitute consultation immediately.

(j) *Conservation recommendations.* The Service may provide with the biological opinion a statement containing discretionary conservation recommendations. Conservation recommendations are advisory and are not intended to carry any binding legal force.

(k) *Incremental steps.* When the action is authorized by a statute that allows the agency to take incremental steps toward the completion of the action, the Service shall, if requested by the Federal agency, issue a biological opinion on the incremental step being considered, including its views on the entire action. Upon the issuance of such a biological opinion, the Federal agency may proceed with or authorize the incremental steps of the action if:

(1) The biological opinion does not conclude that the incremental step would violate section 7(a)(2);

(2) The Federal agency continues consultation with respect to the entire action and obtains biological opinions, as required, for each incremental step;

(3) The Federal agency fulfills its continuing obligation to obtain sufficient data upon which to base the final biological opinion on the entire action;

(4) The incremental step does not violate section 7(d) of the Act concerning irreversible or irretrievable commitment of resources; and

(5) There is a reasonable likelihood that the entire action will not violate section 7(a)(2) of the Act.

(l) *Termination of consultation.* (1) Formal consultation is terminated with the issuance of the biological opinion.

(2) If during any stage of consultation a Federal agency determines that its proposed action is not likely to occur, the consultation may be terminated by written notice to the Service.

(3) If during any stage of consultation a Federal agency determines, with the concurrence of the Director, that its proposed action is not likely to adversely affect any listed species or critical habitat, the consultation is terminated.

§402.15 Responsibilities of Federal agency following issuance of a biological opinion.

(a) Following the issuance of a biological opinion, the Federal agency shall determine whether and in what manner to proceed with the action in light of its section 7 obligations and the Service's biological opinion.

(b) If a jeopardy biological opinion is issued, the Federal agency shall notify the Service of its final decision on the action.

(c) If the Federal agency determines that it cannot comply with the requirements of section 7(a)(2) after consultation with the Service, it may apply for an exemption. Procedures for exemption applications by Federal

agencies and others are found in 50 CFR Part 451.

§402.16 Reinitiation of formal consultation.

Reinitiation of formal consultation is required and shall be requested by the Federal agency or by the Service, where discretionary Federal involvement or control over the action has been retained or is authorized by law and:

(a) If the amount or extent of taking specified in the incidental take statement is exceeded;

(b) If new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered;

(c) If the identified action is subsequently modified in a manner that

causes an effect to the listed species or critical habitat that was not considered in the biological opinion; or

(d) If a new species is listed or critical habitat designated that may be affected by the identified action.

Dated: December 12, 1985.

William P. Horn,

Assistant Secretary for Fish and Wildlife and Parks.

Dated: January 30, 1986.

William G. Gordon,

Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA-HQ-OAR-2007-1145; FRL-9654-4]

RIN 2060-A072

Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Sulfur

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule is being issued as required by a consent decree governing the schedule for completion of this review of the air quality criteria and the secondary national ambient air quality standards (NAAQS) for oxides of nitrogen and oxides of sulfur. Based on its review, the EPA is retaining the current nitrogen dioxide (NO₂) and sulfur dioxide (SO₂) secondary standards to address the direct effects on vegetation of exposure to gaseous oxides of nitrogen and sulfur and, for reasons described in detail in this final preamble, is not adding new standards at this time to address effects associated with the deposition of oxides of nitrogen and sulfur on sensitive aquatic and terrestrial ecosystems. In addition, in this rule the EPA describes a field pilot program being developed to enhance our understanding of the degree of protectiveness that would likely be afforded by a multi-pollutant standard to address deposition-related acidification of sensitive aquatic ecosystems.

DATES: This final rule is effective on June 4, 2012.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2007-1145. All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is

(202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Mrs. Ginger Tennant, Office of Air Quality Planning and Standards (OAQPS), U.S. Environmental Protection Agency, Mail Code C504-06, Research Triangle Park, NC 27711; telephone: 919-541-4072; fax: 919-541-0237; email: tennant.ginger@epa.gov.

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I. Background

A. Legislative Requirements

Two sections of the Clean Air Act (CAA) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. Section 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in her “judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;” “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;” and “for which * * * [the Administrator] plans to issue air quality criteria * * *.” Air quality criteria are intended to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air * * *.” 42 U.S.C. Section 7408(b). Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1) defines a primary standard as one “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”¹ A secondary standard, as defined in Section 109(b)(2), must “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.” Welfare effects as defined in Section 302(h) (42 U.S.C. Section 7602(h)) include, but are not limited to, “effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

In setting standards that are “requisite” to protect public health and

welfare, as provided in Section 109(b), the EPA’s task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, the EPA may not consider the costs of implementing the standards. See generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465–472, 475–76 (2001). Likewise, “[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient air quality standards” (*American Petroleum Institute v. Costle*, 665 F. 2d at 1185). Section 109(d)(1) requires that “not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under Section 108 and the national ambient air quality standards * * * and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate * * *.” Section 109(d)(2) requires that an independent scientific review committee “shall complete a review of the criteria * * * and the national primary and secondary ambient air quality standards * * * and shall recommend to the Administrator any new * * * standards and revisions of existing criteria and standards as may be appropriate * * *.” Since the early 1980’s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC).

B. History of Reviews of NAAQS for Nitrogen Oxides and Sulfur Oxides

1. NAAQS for Oxides of Nitrogen

After reviewing the relevant science on the public health and welfare effects associated with oxides of nitrogen, the EPA promulgated identical primary and secondary NAAQS for NO₂ in April 1971. These standards were set at a level of 0.053 parts per million (ppm) as an annual average (36 FR 8186). In 1982, the EPA published Air Quality Criteria Document for Oxides of Nitrogen (U.S. EPA, 1982), which updated the scientific criteria upon which the initial standards were based. In February 1984, the EPA proposed to retain the standards set in 1971 (49 FR 6866). After taking into account public comments, the EPA published the final decision to retain these standards in June 1985 (50 FR 25532).

The EPA began the most recent previous review of the oxides of nitrogen secondary standards in 1987. In November 1991, the EPA released an updated draft air quality criteria document (AQCD) for CASAC and public review and comment (56 FR

59285), which provided a comprehensive assessment of the available scientific and technical information on health and welfare effects associated with NO₂ and other oxides of nitrogen. The CASAC reviewed the draft document at a meeting held on July 1, 1993, and concluded in a closure letter to the Administrator that the document “provides a scientifically balanced and defensible summary of current knowledge of the effects of this pollutant and provides an adequate basis for the EPA to make a decision as to the appropriate NAAQS for NO₂” (Wolff, 1993). The AQCD for Oxides of Nitrogen was then finalized (U.S. EPA, 1995a). The EPA also prepared a Staff Paper that summarized and integrated the key studies and scientific evidence contained in the revised AQCD for oxides of nitrogen and identified the critical elements to be considered in the review of the NO₂ NAAQS. The CASAC reviewed two drafts of the Staff Paper and concluded in a closure letter to the Administrator that the document provided a “scientifically adequate basis for regulatory decisions on nitrogen dioxide” (Wolff, 1995).

In October 1995, the Administrator announced her proposed decision not to revise either the primary or secondary NAAQS for NO₂ (60 FR 52874; October 11, 1995). A year later, the Administrator made a final determination not to revise the NAAQS for NO₂ after careful evaluation of the comments received on the proposal (61 FR 52852; October 8, 1996). While the primary NO₂ standard was revised in January 2010, by supplementing the existing annual standard with the establishment of a new 1-hour standard, set at a level of 100 parts per billion (ppb) (75 FR 6474), the secondary NAAQS for NO₂ remains 0.053 ppm (100 micrograms per cubic meter [µg/m³] of air), annual arithmetic average, calculated as the arithmetic mean of the 1-hour NO₂ concentrations.

2. NAAQS for Oxides of Sulfur

The EPA promulgated primary and secondary NAAQS for SO₂ in April 1971 (36 FR 8186). The secondary standards included a standard set at 0.02 ppm, annual arithmetic mean, and a 3-hour average standard set at 0.5 ppm, not to be exceeded more than once per year. These secondary standards were established solely on the basis of evidence of adverse effects on vegetation. In 1973, revisions made to Chapter 5 (“Effects of Sulfur Oxide in the Atmosphere on Vegetation”) of the AQCD for Sulfur Oxides (U.S. EPA, 1973) indicated that it could not

¹ The legislative history of Section 109 of the CAA indicates that a primary standard is to be set at “the maximum permissible ambient air level * * * which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group” S. Rep. No. 91–1196, 91st Cong., 2d Sess. 10 (1970).

properly be concluded that the vegetation injury reported resulted from the average SO₂ exposure over the growing season, rather than from short-term peak concentrations. Therefore, the EPA proposed (38 FR 11355) and then finalized (38 FR 25678) a revocation of the annual mean secondary standard. At that time, the EPA was aware that then-current concentrations of oxides of sulfur in the ambient air had other public welfare effects, including effects on materials, visibility, soils, and water. However, the available data were considered insufficient to establish a quantitative relationship between specific ambient concentrations of oxides of sulfur and such public welfare effects (38 FR 25679).

In 1979, the EPA announced that it was revising the AQCD for oxides of sulfur concurrently with that for particulate matter (PM) and would produce a combined PM and oxides of sulfur criteria document. Following its review of a draft revised criteria document in August 1980, CASAC concluded that acid deposition was a topic of extreme scientific complexity because of the difficulty in establishing firm quantitative relationships among (1) Emissions of relevant pollutants (e.g., SO₂ and oxides of nitrogen), (2) formation of acidic wet and dry deposition products, and (3) effects on terrestrial and aquatic ecosystems. The CASAC also noted that acid deposition involves, at a minimum, several different criteria pollutants: oxides of sulfur, oxides of nitrogen, and the fine particulate fraction of suspended particles. The CASAC felt that any document on this subject should address both wet and dry deposition, since dry deposition was believed to account for a substantial portion of the total acid deposition problem.

For these reasons, CASAC recommended that a separate, comprehensive document on acid deposition be prepared prior to any consideration of using the NAAQS as a regulatory mechanism for the control of acid deposition. The CASAC also suggested that a discussion of acid deposition be included in the AQCDs for oxides of nitrogen and PM and oxides of sulfur. Following CASAC closure on the AQCD for oxides of sulfur in December 1981, the EPA published a Staff Paper in November 1982, although the paper did not directly assess the issue of acid deposition. Instead, the EPA subsequently prepared the following documents to address acid deposition: The Acidic Deposition Phenomenon and Its Effects: Critical Assessment Review Papers, Volumes I and II (U.S.

EPA, 1984a, b) and The Acidic Deposition Phenomenon and Its Effects: Critical Assessment Document (U.S. EPA, 1985) (53 FR 14935–14936). These documents, though they were not considered criteria documents and did not undergo CASAC review, represented the most comprehensive summary of scientific information relevant to acid deposition completed by the EPA at that point.

In April 1988 (53 FR 14926), the EPA proposed not to revise the existing primary and secondary standards for SO₂. This proposed decision with regard to the secondary SO₂ NAAQS was due to the Administrator's conclusions that: (1) Based upon the then-current scientific understanding of the acid deposition problem, it would be premature and unwise to prescribe any regulatory control program at that time; and (2) when the fundamental scientific uncertainties had been decreased through ongoing research efforts, the EPA would draft and support an appropriate set of control measures. Although the EPA revised the primary SO₂ standard in June 2010 by establishing a new 1-hour standard at a level of 75 ppb and revoking the existing 24-hour and annual standards (75 FR 35520), no further decision on the secondary SO₂ standard has been published.

C. History of Related Assessments and Agency Actions

In 1980, the Congress created the National Acid Precipitation Assessment Program (NAPAP) in response to growing concern about acidic deposition. The NAPAP was given a broad 10-year mandate to examine the causes and effects of acidic deposition and to explore alternative control options to alleviate acidic deposition and its effects. During the course of the program, the NAPAP issued a series of publicly available interim reports prior to the completion of a final report in 1990 (NAPAP, 1990).

In spite of the complexities and significant remaining uncertainties associated with the acid deposition problem, it soon became clear that a program to address acid deposition was needed. The CAA Amendments of 1990 included numerous separate provisions related to the acid deposition problem. The primary and most important of the provisions, the amendments to Title IV of the Act, established the Acid Rain Program to reduce emissions of SO₂ by 10 million tons and emissions of nitrogen oxides by 2 million tons from 1980 emission levels in order to achieve reductions over broad geographic regions. In this provision, Congress

included a statement of findings that led them to take action, concluding that (1) The presence of acid compounds and their precursors in the atmosphere and in deposition from the atmosphere represents a threat to natural resources, ecosystems, materials, visibility, and public health; (2) the problem of acid deposition is of national and international significance; and (3) current and future generations of Americans will be adversely affected by delaying measures to remedy the problem.

Second, Congress authorized the continuation of the NAPAP in order to assure that the research and monitoring efforts already undertaken would continue to be coordinated and would provide the basis for an impartial assessment of the effectiveness of the Title IV program.

Third, Congress considered that further action might be necessary in the long-term to address any problems remaining after implementation of the Title IV program and, reserving judgment on the form that action could take, included Section 404 of the 1990 Amendments (CAA Amendments of 1990, Pub. L. 101–549, Section 404) requiring the EPA to conduct a study on the feasibility and effectiveness of an acid deposition standard or standards to protect “sensitive and critically sensitive aquatic and terrestrial resources.” At the conclusion of the study, the EPA was to submit a report to Congress. Five years later, the EPA submitted its report, entitled Acid Deposition Standard Feasibility Study: Report to Congress (U.S. EPA, 1995b) in fulfillment of this requirement. That report concluded that establishing acid deposition standards for sulfur and nitrogen deposition may at some point in the future be technically feasible, although appropriate deposition loads for these acidifying chemicals could not be defined with reasonable certainty at that time.

Fourth, the 1990 Amendments also added new language to sections of the CAA pertaining to the scope and application of the secondary NAAQS designed to protect the public welfare. Specifically, the definition of “effects on welfare” in Section 302(h) was expanded to state that the welfare effects include effects “* * * whether caused by transformation, conversion, or combination with other air pollutants.”

In 1999, seven Northeastern states cited this amended language in Section 302(h) in a petition asking the EPA to use its authority under the NAAQS program to promulgate secondary NAAQS for the criteria pollutants

associated with the formation of acid rain. The petition stated that this language “clearly references the transformation of pollutants resulting in the inevitable formation of sulfate and nitrate aerosols and/or their ultimate environmental impacts as wet and dry deposition, clearly signaling Congressional intent that the welfare damage occasioned by sulfur and nitrogen oxides be addressed through the secondary standard provisions of Section 109 of the Act.” The petition further stated that “recent federal studies, including the NAPAP Biennial Report to Congress: An Integrated Assessment, document the continued and increasing damage being inflicted by acid deposition to the lakes and forests of New York, New England and other parts of our nation, demonstrating that the Title IV program had proven insufficient.” The petition also listed other adverse welfare effects associated with the transformation of these criteria pollutants, including impaired visibility, eutrophication of coastal estuaries, global warming, and tropospheric ozone and stratospheric ozone depletion.

In a related matter, the Office of the Secretary of the U.S. Department of Interior (DOI) requested in 2000, that the EPA initiate a rulemaking proceeding to enhance the air quality in national parks and wilderness areas in order to protect resources and values that are being adversely affected by air pollution. Included among the effects of concern identified in the request were the acidification of streams, surface waters, and/or soils; eutrophication of coastal waters; visibility impairment; and foliar injury from ozone.

In a **Federal Register** notice in 2001 (65 FR 48699), the EPA announced receipt of these requests and asked for comment on the issues raised in them. The EPA stated that it would consider any relevant comments and information submitted, along with the information provided by the petitioners and DOI, before making any decision concerning a response to these requests for rulemaking.

The 2005 NAPAP report states that “* * * scientific studies indicate that the emission reductions achieved by Title IV are not sufficient to allow recovery of acid-sensitive ecosystems. Estimates from the literature of the scope of additional emission reductions that are necessary in order to protect acid-sensitive ecosystems range from approximately 40–80 percent beyond full implementation of Title IV * * *.” The results of the modeling presented in this Report to Congress indicate that broader recovery is not predicted

without additional emission reductions (NAPAP, 2005).

Given the state of the science as described in the Integrated Science Assessment (ISA), Risk and Exposure Assessment (REA), and in other recent reports, such as the NAPAP reports noted above, the EPA has decided, in the context of evaluating the adequacy of the current NO₂ and SO₂ secondary standards in this review, to revisit the question of the appropriateness of setting secondary NAAQS to address remaining known or anticipated adverse public welfare effects resulting from the acidic and nutrient deposition of these criteria pollutants.

D. History of the Current Review

The EPA initiated this current review in December 2005, with a call for information (70 FR 73236) for the development of a revised ISA. An Integrated Review Plan (IRP) was developed to provide the framework and schedule as well as the scope of the review and to identify policy-relevant questions to be addressed in the components of the review. The IRP was released in 2007 (U.S. EPA, 2007) for CASAC and public review. The EPA held a workshop in July 2007 on the ISA to obtain broad input from the relevant scientific communities. This workshop helped to inform the preparation of the first draft ISA, which was released for CASAC and public review in December 2007; a CASAC meeting was held on April 2–3, 2008, to review the first draft ISA. A second draft ISA was released for CASAC and public review in August 2008, and was discussed at a CASAC meeting held on October 1–2, 2008. The final ISA (U.S. EPA, 2008) was released in December 2008.

Based on the science presented in the ISA, the EPA developed the REA to further assess the national impact of the effects documented in the ISA. The Draft Scope and Methods Plan for Risk/Exposure Assessment: Secondary NAAQS Review for Oxides of Nitrogen and Oxides of Sulfur outlining the scope and design of the future REA was prepared for CASAC consultation and public review in March 2008. A first draft REA was presented to CASAC and the public for review in August 2008, and a second draft was presented for review in June 2009. The final REA (U.S. EPA, 2009) was released in September 2009. A first draft Policy Assessment (PA) was released in March 2010, and reviewed by CASAC on April 1–2, 2010. In a June 22, 2010, letter to the Administrator, CASAC provided advice and recommendations to the Agency concerning the first draft PA (Russell and Samet, 2010a). A second

draft PA was released to CASAC and the public in September 2010, and reviewed by CASAC on October 6–7, 2010. The CASAC provided advice and recommendations to the Agency regarding the second draft PA in a December 9, 2010 letter (Russell and Samet 2010b). The CASAC and public comments on the second draft PA were considered by the EPA staff in developing a final PA (U.S. EPA, 2011). CASAC requested an additional meeting to provide additional advice to the Administrator based on the final PA on February 15–16, 2011. On January 14, 2011 the EPA released a version of the final PA prior to final document production, to provide sufficient time for CASAC review of the document in advance of this meeting. The final PA, incorporating final reference checks and document formatting, was released in February 2011. In a May 17, 2011, letter (Russell and Samet, 2011a), CASAC offered additional advice and recommendations to the Administrator with regard to the review of the secondary NAAQS for oxides of nitrogen and oxides of sulfur.

In 2005, the Center for Biological Diversity and four other plaintiffs filed a complaint alleging that the EPA had failed to complete the current review within the period provided by statute.² The schedule for completion of this review is governed by a consent decree resolving that lawsuit and the subsequent extension agreed to by the parties. The schedule presented in the original consent decree that governs this review, entered by the court on November 19, 2007, was revised on October 22, 2009 to allow for a 17-month extension of the schedule. The current decree provides that the EPA sign for publication notices of proposed and final rulemaking concerning its review of the oxides of nitrogen and oxides of sulfur NAAQS no later than July 12, 2011 and March 20, 2012, respectively.

This action presents the Administrator's final decisions on the review of the current secondary oxides of nitrogen and oxides of sulfur standards. Throughout this preamble a number of conclusions, findings, and determinations by the Administrator are noted.

E. Scope of the Current Review

1. Scope Presented in the Proposal

In conducting this periodic review of the secondary NAAQS for oxides of nitrogen and oxides of sulfur, as discussed in the IRP and REA, the EPA

² Center for Biological Diversity, et al. v. Johnson, No. 05–1814 (D.D.C.).

decided to assess the scientific information, associated risks, and standards relevant to protecting the public welfare from adverse effects associated jointly with oxides of nitrogen and sulfur. Although the EPA has historically adopted separate secondary standards for oxides of nitrogen and oxides of sulfur, the EPA is conducting a joint review of these standards because oxides of nitrogen and sulfur, and their associated transformation products are linked from an atmospheric chemistry perspective, as well as from an environmental effects perspective. The National Research Council (NRC) has recommended that the EPA consider multiple pollutants, as appropriate, in forming the scientific basis for the NAAQS (NRC, 2004). As discussed in the ISA and REA, there is a strong basis for considering these pollutants together, building upon the EPA's past recognition of the interactions of these pollutants and on the growing body of scientific information that is now available related to these interactions and associated ecological effects.

In defining the scope of this review, it must be considered that the EPA has set secondary standards for two other criteria pollutants related to oxides of nitrogen and sulfur: ozone (O₃) and PM. Oxides of nitrogen are precursors to the formation of ozone in the atmosphere, and under certain conditions, can combine with atmospheric ammonia to form ammonium nitrate, a component of fine PM. Oxides of sulfur are precursors to the formation of particulate sulfate, which is a significant component of fine PM in many parts of the United States. There are a number of welfare effects directly associated with ozone and fine PM, including ozone-related damage to vegetation and PM-related visibility impairment. Protection against those effects is provided by the ozone and fine PM secondary standards. This review focuses on evaluation of the protection provided by secondary standards for oxides of nitrogen and sulfur for two general types of effects: (1) direct effects on vegetation associated with exposure to gaseous oxides of nitrogen and sulfur in the ambient air, which are the effects that the current NO₂ and SO₂ secondary standards protect against; and (2) effects associated with the deposition of oxides of nitrogen and sulfur to sensitive aquatic and terrestrial ecosystems, including deposition in the form of particulate nitrate and particulate sulfate.

The ISA focuses on the ecological effects associated with deposition of ambient oxides of nitrogen and sulfur to natural sensitive ecosystems, as

distinguished from commercially managed forests and agricultural lands. This focus reflects the fact that the majority of the scientific evidence regarding acidification and nutrient enrichment is based on studies in unmanaged ecosystems. Non-managed terrestrial ecosystems tend to have a higher fraction of nitrogen deposition resulting from atmospheric nitrogen (U.S. EPA, 2008, section 3.3.2.5). In addition, the ISA notes that agricultural and commercial forest lands are routinely fertilized with amounts of nitrogen that exceed air pollutant inputs even in the most polluted areas (U.S. EPA, 2008, section 3.3.9). This review recognizes that the effects of nitrogen deposition in managed areas are viewed differently from a public welfare perspective than are the effects of nitrogen deposition in natural, unmanaged ecosystems, largely due to the more homogeneous, controlled nature of species composition and development in managed ecosystems and the potential for benefits of increased productivity in those ecosystems.

In focusing on natural sensitive ecosystems, the PA primarily considers the effects of ambient oxides of nitrogen and sulfur via deposition on multiple ecological receptors. The ISA highlights effects including those associated with acidification and nitrogen nutrient enrichment. With a focus on these deposition-related effects the EPA's objective is to develop a framework for oxides of nitrogen and sulfur standards that incorporates ecologically relevant factors and that recognizes the interactions between the two pollutants as they deposit to sensitive ecosystems. The overarching policy objective is to develop a secondary standard(s) based on the ecological criteria described in the ISA and the results of the assessments in the REA, and consistent with the requirement of the CAA to set secondary standards that are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of these air pollutants in the ambient air. Consistent with the CAA, this policy objective includes consideration of "variable factors * * * which of themselves or in combination with other factors may alter the effects on public welfare" of the criteria air pollutants included in this review.

In addition, we have chosen to focus on the effects of ambient oxides of nitrogen and sulfur on ecological impacts on sensitive aquatic ecosystems associated with acidifying deposition of nitrogen and sulfur, which is a transformation product of ambient

oxides of nitrogen and sulfur. Based on the information in the ISA, the assessments presented in the REA, and advice from CASAC on earlier drafts of this PA (Russell and Samet, 2010a, 2010b), and as discussed in detail in the PA, we have the greatest confidence in the causal linkages between oxides of nitrogen and sulfur and aquatic acidification effects relative to other deposition-related effects, including terrestrial acidification and aquatic and terrestrial nutrient enrichment.

2. Comments on the Scope of the Review

Comments received regarding the scope of the review were primarily those that questioned the EPA's legal authority under Section 109 of the CAA to set NAAQS that address deposition-related effects, focusing in particular on effects resulting from acidifying deposition to ecosystems.

While environmental organizations and some other commenters urged the EPA to establish a NAAQS that would protect against the impacts on sensitive ecosystems associated with the acidifying deposition of nitrogen and sulfur, several industry commenters argued that the enactment of Title IV of the CAA in 1990 displaced the EPA's authority to address acidification through the setting of NAAQS. These commenters contend that the existence of a specific regulatory program to address the acidification effects of oxides of nitrogen and sulfur supplants the EPA's general authority under the CAA. According to industry comments, this is demonstrated by a close reading of Section 404 which required the EPA to report to Congress on the feasibility of developing an acid deposition standard and the actions that would be required to integrate such a program into the CAA. The required study described in Section 404, commenters argue, demonstrates that Congress had concluded that the EPA lacked the authority under Section 109 of the CAA to establish a secondary NAAQS to address acid deposition.

Although the EPA is not adopting a secondary standard designed to protect the public welfare from the effects associated with the acidifying deposition of nitrogen and sulfur, the EPA does not agree that the enactment of Title IV displaced the EPA's authority under Section 109 of the CAA to set such a NAAQS. We note that the purpose of Title IV "is to reduce the adverse effects of acid deposition," CAA Section 401(b), while Section 109 directs the Administrator to go beyond this to set a standard that is "requisite to protect public welfare from any known or

anticipated adverse effects,” CAA Section 109(b)(2). These provisions are not accordingly in conflict, but represent the often typical interlinked approach of Congress to address the frequently complex problems of air pollution.

Nothing in the text or the legislative history of Title IV of the Act indicates a clear intention by Congress to foreclose the EPA’s authority to address acid deposition through the NAAQS process. The requirement in Section 404 of the 1990 CAA Amendments that the EPA send to Congress “a report on the feasibility and effectiveness of an acid deposition standard or standards” does not indicate that Congress had concluded that an amendment to the CAA would be necessary to give the EPA the authority to issue regulations addressing acidification. The significance of the report required by Section 404 cannot be understood clearly in isolation, but should be considered in the overall context of the history of Congress’ and the EPA’s attempts to understand and to address the causes and effects of acid deposition and the EPA’s conclusion in 1988 that the scientific uncertainties associated with acid deposition were too great to allow the Agency to establish a secondary NAAQS at that time. In the proposed rule, we noted that it was clear at the time of the 1990 CAA Amendments that a program to address acid deposition was needed and that the primary and most important of these provisions is Title IV of the Act, establishing the Acid Rain Program. In assessing the import of Section 404 in this overall context, the EPA has noted in the past and in section I.C above that “Congress reserved judgment as to whether further action might be necessary or appropriate in the longer term” to address any problems remaining after implementation of the Title IV program, and “if so, what form it should take” (58 FR 21351, 21356 (April 21, 1993)). Such reservation of judgment does not indicate that Congress viewed the EPA as lacking authority under Section 109 to establish a secondary NAAQS to address acid deposition but a recognition that the uncertainties associated with such a standard may be too significant to allow the Administrator to reach a reasoned conclusion as to the appropriate standard.

Having carefully considered the public comments, the EPA finds that the conclusions reached in the proposed rule with regard to the scope of the current review continue to be valid. The EPA concludes that the Agency has the authority under Section 109 of the CAA

to consider deposition-related to ambient air concentrations of oxides of nitrogen and sulfur and the resulting effects on ecosystems and that the focus of the current review of the NAAQS for oxides of nitrogen and sulfur on aquatic acidification is appropriate. This issue is discussed in more detail in the EPA’s Response to Comments document.

II. Rationale for Final Decisions on the Adequacy of the Current Secondary Standards

This section presents the rationale for the Administrator’s final conclusions with regard to the adequacy of protection and ecological relevance of the current secondary standards for oxides of nitrogen and sulfur. As discussed more fully below, this rationale considered the latest scientific information on ecological effects associated with the presence of oxides of nitrogen and oxides of sulfur in the ambient air. This rationale also takes into account: (1) Staff assessments of the most policy-relevant information in the ISA and staff analyses of air quality, exposure, and ecological risks, presented more fully in the REA and in the PA, upon which staff conclusions on revisions to the secondary oxides of nitrogen and oxides of sulfur standards are based; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA, REA, and PA at public meetings, in separate written comments, and in CASAC’s letters to the Administrator; and (3) public comments received during the development of these documents, either in connection with CASAC meetings or separately as well as comments received on the proposal notice.

In developing this rationale, the EPA has drawn upon an integrative synthesis of the entire body of evidence, published through early 2008, on ecological effects associated with the deposition of oxides of nitrogen and oxides of sulfur in the ambient air (U.S. EPA, 2008). As discussed below, this body of evidence addresses a broad range of ecological endpoints associated with ambient levels of oxides of nitrogen and oxides of sulfur. In considering this evidence, the EPA focuses on those ecological endpoints, such as aquatic acidification, for which the ISA judges associations with oxides of nitrogen and oxides of sulfur to be causal, likely causal, or for which the evidence is suggestive that oxides of nitrogen and/or sulfur contribute to the reported effects. The categories of causality determinations have been developed in the ISA (U.S. EPA, 2008) and are discussed in section 1.6 of the ISA.

Decisions on retaining or revising the current secondary standards for oxides of nitrogen and sulfur are largely public welfare policy judgments based on the Administrator’s informed assessment of what constitutes requisite protection against adverse effects to public welfare. A public welfare policy decision should draw upon scientific information and analyses about welfare effects, exposure and risks, as well as judgments about the appropriate response to the range of uncertainties that are inherent in the scientific evidence and analyses. The ultimate determination as to what level of damage to ecosystems and the services provided by those ecosystems is adverse to public welfare is not wholly a scientific question, although it is informed by scientific studies linking ecosystem damage to losses in ecosystem services, and information on the value of those losses of ecosystem services. In reaching such decisions, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose.

Drawing from information in sections II.A–C of the proposal, section II.A below provides overviews of the public welfare effects considered in this review, the risk and exposure assessments, and the adversity of effects on public welfare. Section II.B presents conclusions in the ISA, REA, and PA on the adequacy of the current secondary standards for oxides of nitrogen and oxides of sulfur. Consideration is given to the adequacy of protection afforded by the current standards for both direct and deposition-related effects, as well as to the appropriateness of the fundamental structure and the basic elements of the current standards for providing protection from deposition-related effects. The views of CASAC and a summary of the Administrator’s proposed conclusions are also included. Section II. C presents a discussion of the comments received on the proposal with regard to the adequacy of the current standards. Section II. D presents the Administrator’s final decisions with regard to the adequacy of the current standards for both direct and deposition-related effects on public welfare.

A. Introduction

A discussion of the effects associated with oxides of nitrogen and sulfur in the ambient air is presented below in section II.A.1. The discussion is organized around the types of effects being considered, including direct effects of gaseous oxides of nitrogen and sulfur, deposition-related effects related to acidification and nutrient

enrichment, and other effects such as materials damage, climate-related effects and mercury methylation.

Section II.A.2 presents a summary and discussion of the risk and exposure assessment performed for each of the four major effects categories. The REA uses case studies representing the broad geographic variability of the impacts from oxides of nitrogen and sulfur to conclude that there are ongoing adverse effects in many ecosystems from deposition of oxides of nitrogen and sulfur and that under current emissions scenarios these effects are likely to continue.

Section II.A.3 presents a discussion of adversity linking ecological effects to measures that can be used to characterize the extent to which such effects are reasonably considered to be adverse to public welfare. This involves consideration of how to characterize adversity from a public welfare perspective. In so doing, consideration is given to the concept of ecosystem services, the evidence of effects on ecosystem services, and how ecosystem services can be linked to ecological indicators.

1. Overview of Effects

This section discusses the known or anticipated ecological effects associated with oxides of nitrogen and sulfur, including the direct effects of gas-phase exposure to oxides of nitrogen and sulfur (section II.A.1.a) and effects associated with deposition-related exposure (section II.A.1.b). These sections also address questions about the nature and magnitude of ecosystem responses to reactive nitrogen and sulfur deposition, including responses related to acidification, nutrient depletion, and the mobilization of toxic metals in sensitive aquatic and terrestrial ecosystems. The uncertainties and limitations associated with the evidence of such effects are also discussed throughout this section.

a. Effects Associated With Gas-Phase Oxides of Nitrogen and Sulfur

Ecological effects on vegetation as discussed in earlier reviews as well as the ISA can be attributed to gas-phase oxides of nitrogen and sulfur. Acute and chronic exposures to gaseous pollutants such as SO₂, NO₂, nitric oxide (NO), nitric acid (HNO₃) and peroxyacetyl nitrite (PAN) are associated with negative impacts to vegetation. The current secondary NAAQS were set to protect against direct damage to vegetation by exposure to gas-phase oxides of nitrogen and sulfur, such as foliar injury, decreased photosynthesis, and decreased growth. The following

summary is a concise overview of the known or anticipated effects to vegetation caused by gas phase nitrogen and sulfur. Most phototoxic effects associated with gas phase oxides of nitrogen and sulfur occur at levels well above ambient concentrations observed in the United States (U.S. EPA, 2008, section 3.4.2.4).

The 2008 ISA found that gas phase nitrogen and sulfur are associated with direct phytotoxic effects (U.S. EPA, 2008, section 4.4). The evidence is sufficient to infer a causal relationship between exposure to SO₂ and injury to vegetation (U.S. EPA, 2008, section 4.4.1 and 3.4.2.1). Acute foliar injury to vegetation from SO₂ may occur at levels above the current secondary standard (3-h average of 0.50 ppm). Effects on growth, reduced photosynthesis and decreased yield of vegetation are also associated with increased SO₂ exposure concentration and time of exposure.

The evidence is sufficient to infer a causal relationship between exposure to NO, NO₂ and PAN and injury to vegetation (U.S. EPA, 2008, section 4.4.2 and 3.4.2.2). At sufficient concentrations, NO, NO₂ and PAN can decrease photosynthesis and induce visible foliar injury to plants. Evidence is also sufficient to infer a causal relationship between exposure to HNO₃ and changes to vegetation (U.S. EPA, 2008, section 4.4.3 and 3.4.2.3). Phytotoxic effects of this pollutant include damage to the leaf cuticle in vascular plants and disappearance of some sensitive lichen species.

Vegetation in ecosystems near sources of gaseous oxides of nitrogen and sulfur or where SO₂, NO, NO₂, PAN and HNO₃ are most concentrated are more likely to be impacted by these pollutants. Uptake of these pollutants in a plant canopy is a complex process involving adsorption to surfaces (leaves, stems and soil) and absorption into leaves (U.S. EPA, 2008, section 3.4.2). The functional relationship between ambient concentrations of gas phase oxides of nitrogen and sulfur and specific plant response are impacted by internal factors such as rate of stomatal conductance and plant detoxification mechanisms, and external factors including plant water status, light, temperature, humidity, and pollutant exposure regime (U.S. EPA, 2008, section 3.4.2).

Entry of gases into a leaf is dependent upon physical and chemical processes of gas phase as well as to stomatal aperture. The aperture of the stomata is controlled largely by the prevailing environmental conditions, such as water availability, humidity, temperature, and light intensity. When the stomata are

closed, resistance to gas uptake is high and the plant has a very low degree of susceptibility to injury. Mosses and lichens do not have a protective cuticle barrier to gaseous pollutants or stomata and are generally more sensitive to gaseous sulfur and nitrogen than vascular plants (U.S. EPA, 2008, section 3.4.2).

The appearance of foliar injury can vary significantly across species and growth conditions affecting stomatal conductance in vascular plants (U.S. EPA, 2009, section 6.4.1). For example, damage to lichens from SO₂ exposure includes decreased photosynthesis and respiration, damage to the algal component of the lichen, leakage of electrolytes, inhibition of nitrogen fixation, decreased potassium (K⁺) absorption, and structural changes.

The phytotoxic effects of gas phase oxides of nitrogen and sulfur are dependent on the exposure concentration and duration and species sensitivity to these pollutants. Effects to vegetation associated with oxides of nitrogen and sulfur are therefore variable across the United States and tend to be higher near sources of photochemical smog. For example, SO₂ is considered to be the primary factor contributing to the death of lichens in many urban and industrial areas.

The ISA states there is very limited new research on phytotoxic effects of NO, NO₂, PAN and HNO₃ at concentrations currently observed in the United States with the exception of some lichen species (U.S. EPA, 2008, section 4.4). Past and current HNO₃ concentrations may be contributing to the decline in lichen species in the Los Angeles basin. Most phytotoxic effects associated with gas phase oxides of nitrogen and sulfur occur at levels well above ambient concentrations observed in the United States (U.S. EPA, 2008, section 3.4.2.4).

b. Effects Associated With Deposition of Oxides of Nitrogen and Sulfur

Ecological effects associated with the deposition of oxides of nitrogen and oxides of sulfur can be divided into endpoints related to the type of ecosystem affected and the type of effect. As more fully discussed in section II.A of the proposal and chapter 3 of the PA, this section provides a brief summary of effects on ecosystems related to acidification, nutrient enrichment, and metal toxicity.

i. Acidification Effects on Aquatic and Terrestrial Ecosystems

Sulfur oxides and nitrogen oxides in the atmosphere undergo a complex mix of reactions in gaseous, liquid, and solid

phases to form various acidic compounds. These acidic compounds are removed from the atmosphere through deposition: either wet (e.g., rain, snow), fog or cloud, or dry (e.g., gases, particles). Deposition of these acidic compounds to aquatic and terrestrial ecosystems can lead to effects on ecosystem structure and function. Following deposition, these compounds can, in some instances, unless retained by soil or biota, leach out of the soils in the form of sulfate (SO_4^{2-}) and nitrate (NO_3^-), leading to the acidification of surface waters. The effects on ecosystems depend on the magnitude and rate of deposition, as well as a host of biogeochemical processes occurring in the soils and water bodies (U.S. EPA, 2009, section 2.1). The chemical forms of nitrogen that may contribute to acidifying deposition include both oxidized and reduced chemical species, including reduced forms of nitrogen (NH_x).

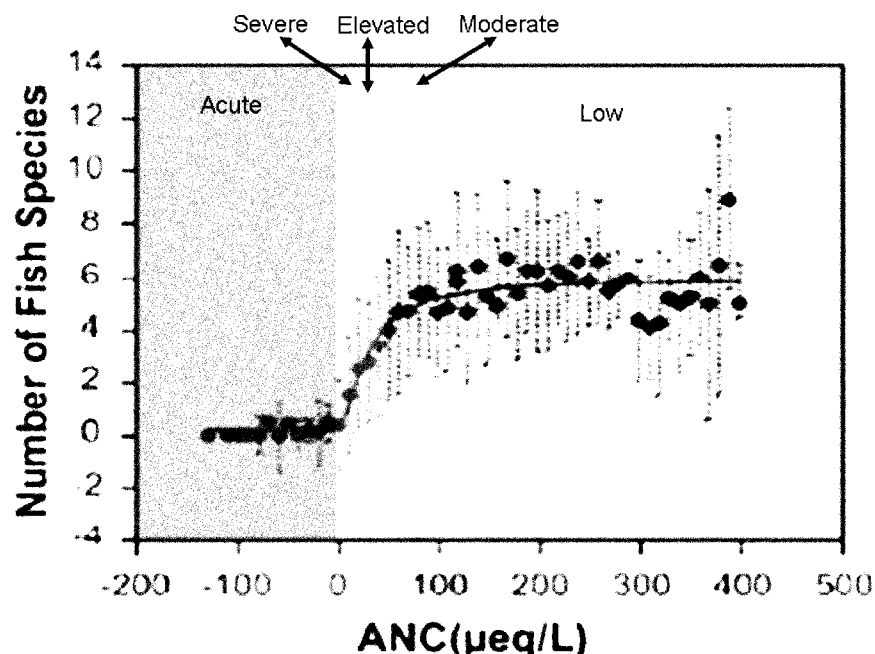
The ISA concluded that deposition of oxides of nitrogen and sulfur and NH_x leads to the varying degrees of acidification of ecosystems (U.S. EPA, 2008). In the process of acidification, biogeochemical components of terrestrial and freshwater aquatic ecosystems are altered in a way that leads to effects on biological organisms. Deposition to terrestrial ecosystems often moves through the soil and eventually leaches into adjacent water bodies. Principal factors governing the sensitivity of terrestrial and aquatic ecosystems to acidification from sulfur and nitrogen deposition include geology, plant uptake of nitrogen, soil depth, and elevation. Geologic formations having low base cation supply generally underlie the watersheds of acid-sensitive lakes and

streams. Other factors that contribute to the sensitivity of soils and surface waters to acidifying deposition include topography, soil chemistry, land use, and hydrologic flowpath. Chronic as well as episodic acidification tends to occur primarily at relatively high elevations in areas that have base-poor bedrock, high relief, and shallow soils.

With regard to aquatic acidification, the ISA concluded that the scientific evidence is sufficient to infer a causal relationship between acidifying deposition and effects on biogeochemistry and biota in aquatic ecosystems (U.S. EPA, 2008, section 4.2.2). The strongest evidence comes from studies of surface water chemistry in which acidic deposition is observed to alter sulfate and nitrate concentrations in surface waters, the sum of base cations, acid neutralizing capacity (ANC), dissolved inorganic aluminum (Al) and pH (U.S. EPA, 2008, section 3.2.3.2). The ANC is a key indicator of acidification with relevance to both terrestrial and aquatic ecosystems. The ANC is useful because it integrates the overall acid-base status of a lake or stream and reflects how aquatic ecosystems respond to acidic deposition over time. There is also a relationship between ANC and the surface water constituents that directly contribute to or ameliorate acidity-related stress, in particular, concentrations of hydrogen ion (as pH), calcium (Ca^{2+}) and Al. Moreover, low pH surface waters leach aluminum from soils, which is quite lethal to fish and other aquatic organisms. In aquatic systems, there is a direct relationship between ANC and fish and phyto-zooplankton diversity and abundance. Acidification in terrestrial ecosystems has been shown to cause decreased

growth and increased susceptibility to disease and injury in sensitive tree species, including red spruce and sugar maple.

Based on analyses of surface water data from freshwater ecosystem surveys and monitoring, the most sensitive lakes and streams are contained in New England, the Adirondack Mountains, the Appalachian Mountains (northern Appalachian Plateau and Ridge/Blue Ridge region), the mountainous West, and the Upper Midwest. ANC is the most widely used indicator of acid sensitivity and has been found in various studies to be the best single indicator of the biological response and health of aquatic communities in acid sensitive systems. Annual or multi-year average ANC is a good overall indicator of sensitivity, capturing the ability of an ecosystem to withstand chronic acidification as well as episodic events such as spring melting that can lower ANC over shorter time spans. Biota are generally not harmed when annual average ANC levels are >100 microequivalents per liter ($\mu\text{eq/L}$). At annual average ANC levels between 100 and $50 \mu\text{eq/L}$, the fitness of sensitive species (e.g., brook trout, zooplankton) begins to decline. When annual average ANC is $<50 \mu\text{eq/L}$, negative effects on aquatic biota are observed, including large reductions in diversity of fish species, and declines in health of fish populations, affecting reproductive ability and fitness. Annual average ANC levels below $0 \mu\text{eq/L}$ are generally associated with complete loss of fish species and other biota that are sensitive to acidification. An example of the relationship between ANC level and aquatic effects based on lakes in the Adirondacks is illustrated in the following figure:



Recent studies indicate that acidification of lakes and streams can result in significant loss in economic value, which is one indicator of adversity associated with loss of ecosystem services. A 2006 study of New York residents found that they are willing to pay between \$300 and \$800 million annually for the equivalent of improving lakes in the Adirondacks region to an ANC level of 50 $\mu\text{eq/L}$. Several states have set goals for improving the acid status of lakes and streams, generally targeting ANC in the range of 50 to 60 $\mu\text{eq/L}$, and have engaged in costly activities to decrease acidification.

With regard to terrestrial ecosystems, the evidence is sufficient to infer a causal relationship between acidifying deposition and changes in biogeochemistry (U.S. EPA, 2008, section 4.2.1.1). The strongest evidence comes from studies of forested ecosystems, with supportive information on other plant taxa, including shrubs and lichens (U.S. EPA, 2008, section 3.2.2.1.). Three useful indicators of chemical changes and acidification effects on terrestrial ecosystems, showing consistency among multiple studies are: soil base saturation, Al concentrations in soil water, and soil carbon to nitrogen (C:N) ratio (U.S. EPA, 2008, section 3.2.2.2).

Forests of the Adirondack Mountains of New York, Green Mountains of Vermont, White Mountains of New Hampshire, the Allegheny Plateau of Pennsylvania, and high-elevation forest ecosystems in the southern Appalachians and mountainous regions

in the West are the regions most sensitive to acidifying deposition. The health of at least a portion of the sugar maple and red spruce growing in the United States may have been compromised by acidifying total nitrogen and sulfur deposition in recent years. Soil acidification caused by acidic deposition has been shown to cause decreased growth and increased susceptibility to disease and injury in sensitive tree species. Red spruce dieback or decline has been observed across high elevation areas in the Adirondack, Green and White mountains. The frequency of freezing injury to red spruce needles has increased over the past 40 years, a period that coincided with increased emissions of sulfur and nitrogen oxides and increased acidifying deposition. Acidifying deposition can contribute to dieback in sugar maple through depletion of cations from soil with low levels of available calcium. Grasslands are likely less sensitive to acidification than forests due to grassland soils being generally rich in base cations.

A commonly used indicator of terrestrial acidification is the base cation-to-aluminum ratio, Bc/Al. Many locations in sensitive areas of the United States have Bc/Al levels below benchmark levels we have classified as providing low to intermediate levels of protection to tree health. At a Bc/Al ratio of 1.2 (intermediate level of protection), red spruce growth can be reduced by 20 percent. At a Bc/Al ratio of 0.6 (low level of protection), sugar maple growth can be reduced by 20 percent. While not defining whether a

20 percent reduction in growth can be considered significant, existing economic studies suggest that avoiding significant declines in the health of spruce and sugar maple forests may be worth billions of dollars to residents of the Eastern United States.

ii. Nutrient Enrichment Effects in Terrestrial and Aquatic Ecosystems

The ISA found that deposition of nitrogen, including oxides of nitrogen and NH_x , leads to the nitrogen enrichment of terrestrial, freshwater and estuarine ecosystems (U.S. EPA 2008). In the process of nitrogen enrichment, biogeochemical components of terrestrial and freshwater aquatic ecosystems are altered in a way that leads to effects on biological organisms. Nitrogen deposition is a major source of anthropogenic nitrogen. For many terrestrial and freshwater ecosystems other sources of nitrogen including fertilizer and waste treatment are greater than deposition. Nitrogen deposition often contributes to nitrogen-enrichment effects in estuaries, but does not drive the effects since other sources of nitrogen greatly exceed nitrogen deposition. Both oxides of nitrogen and NH_x contribute to nitrogen deposition. For the most part, nitrogen effects on ecosystems do not depend on whether the nitrogen is in oxidized or reduced form. Thus, this summary focuses on the effects of nitrogen deposition in total.

The numerous ecosystem types that occur across the United States have a broad range of sensitivity to nitrogen deposition. Organisms in their natural

environment are commonly adapted to a specific regime of nutrient availability. Change in the availability of one important nutrient, such as nitrogen, may result in imbalances in ecosystems, with effects on ecosystem processes, structure and function. In certain nitrogen-limited ecosystems, including many ecosystems managed for commercial production, nitrogen deposition can result in beneficial increases in productivity. Nutrient enrichment effects from deposition of oxides of nitrogen are difficult to disentangle from overall effects of nitrogen enrichment. This is caused by two factors: the inputs of reduced nitrogen from deposition and, in estuarine ecosystems, a large fraction of nitrogen inputs from non-atmospheric sources.

The numerous ecosystem types that occur across the United States have a broad range of sensitivity to nitrogen deposition (U.S. EPA, 2008, Table 4–4). Increased deposition to nitrogen-limited ecosystems can lead to production increases that may be either beneficial or adverse depending on the system and management goals. Organisms in their natural environment are commonly adapted to a specific regime of nutrient availability. Change in the availability of one important nutrient, such as nitrogen, may result in an imbalance in ecological stoichiometry, with effects on ecosystem processes, structure and function.

With regard to terrestrial ecosystems, the ISA concluded that the evidence is sufficient to infer a causal relationship between nitrogen deposition and the alteration of biogeochemical cycling in terrestrial ecosystems (U.S. EPA, 2008, section 4.3.1.1 and 3.3.2.1). Due to the complexity of interactions between the nitrogen and carbon cycling, the effects of nitrogen on carbon budgets (quantified input and output of carbon to the ecosystem) are variable. Regional trends in net ecosystem productivity (NEP) of forests (not managed for silviculture) have been estimated through models based on gradient studies and meta-analysis. Atmospheric nitrogen deposition has been shown to cause increased litter accumulation and carbon storage in above-ground woody biomass. In the West, this has led to increased susceptibility to more severe fires. Less is known regarding the effects of nitrogen deposition on carbon budgets of non-forest ecosystems. The ISA also concludes that the evidence is sufficient to infer a causal relationship between nitrogen deposition on the alteration of species richness, species composition and biodiversity in

terrestrial ecosystems (U.S. EPA, 2008, section 4.3.1.2).

Little is known about the full extent and distribution of the terrestrial ecosystems in the United States that are most sensitive to impacts caused by nutrient enrichment from atmospheric nitrogen deposition. Effects are most likely to occur where areas of relatively high atmospheric N deposition intersect with nitrogen-limited plant communities. The alpine ecosystems of the Colorado Front Range, chaparral watersheds of the Sierra Nevada, lichen and vascular plant communities in the San Bernardino Mountains and the Pacific Northwest, and the southern California coastal sage scrub (CSS) community are among the most sensitive terrestrial ecosystems. There is growing evidence (U.S. EPA, 2008, section 4.3.1.2) that existing grassland ecosystems in the western United States are being altered by elevated levels of N inputs, including inputs from atmospheric deposition.

More is known about the sensitivity of particular plant communities. Based largely on results obtained in more extensive studies conducted in Europe, it is expected that the more sensitive terrestrial ecosystems include hardwood forests, alpine meadows, arid and semi-arid lands, and grassland ecosystems (U.S. EPA, 2008, section 3.3.5). The REA used published research results (U.S. EPA, 2009, section 5.3.1 and U.S. EPA, 2008, Table 4.4) to identify meaningful ecological benchmarks associated with different levels of atmospheric nitrogen deposition. These are illustrated in Figure 3–4 of the PA. The sensitive areas and ecological indicators identified by the ISA were analyzed further in the REA to create a national map that illustrates effects observed from ambient and experimental atmospheric nitrogen deposition loads in relation to Community Multi-scale Air Quality (CMAQ) 2002 modeling results and National Atmospheric Deposition Program (NADP) monitoring data. This map, reproduced in Figure 3–5 of the PA, depicts the sites where empirical effects of terrestrial nutrient enrichment have been observed and site proximity to elevated atmospheric nitrogen deposition.

With regard to freshwater ecosystems, the ISA concluded that the evidence is sufficient to infer a causal relationship between nitrogen deposition and the alteration of biogeochemical cycling in freshwater aquatic ecosystems (U.S. EPA, 2008, section 3.3.2.3). Nitrogen deposition is the main source of nitrogen enrichment to headwater streams, lower order streams and high elevation lakes. The ISA also concludes

that the evidence is sufficient to infer a causal relationship between nitrogen deposition and the alteration of species richness, species composition and biodiversity in freshwater aquatic ecosystems (U.S. EPA, 2008, section 3.3.5.3).

There are many examples of fresh waters that are nitrogen-limited or nitrogen and phosphorous (P) co-limited (U.S. EPA, 2008, section 3.3.3.2). Less is known about the extent and distribution of the terrestrial ecosystems in the United States that are most sensitive to the effects of nutrient enrichment from atmospheric nitrogen deposition compared to acidification. Grasslands in the western United States are typically nitrogen-limited ecosystems dominated by a diverse mix of perennial forbs and grass species. A meta-analysis discussed in the ISA (U.S. EPA, 2008, section 3.3.3), indicated that nitrogen fertilization increased aboveground growth in all non-forest ecosystems except for deserts. Because the productivity of estuarine and near shore marine ecosystems is generally limited by the availability of nitrogen, they are also susceptible to the eutrophication effect of nitrogen deposition (U.S. EPA, 2008, section 4.3.4.1).

The magnitude of ecosystem response to nutrient enrichment may be thought of on two time scales, current conditions and how ecosystems have been altered since the onset of anthropogenic nitrogen deposition. As noted previously, studies found that nitrogen-limitation occurs as frequently as phosphorous-limitation in freshwater ecosystems (U.S. EPA, 2008, section 3.3.3.2). Recently, a comprehensive study of available data from the northern hemisphere surveys of lakes along gradients of nitrogen deposition show increased inorganic nitrogen concentration and productivity to be correlated with atmospheric nitrogen deposition. The results are unequivocal evidence of nitrogen limitation in lakes with low ambient inputs of nitrogen, and increased nitrogen concentrations in lakes receiving nitrogen solely from atmospheric nitrogen deposition. It has been suggested that most lakes in the northern hemisphere may have originally been nitrogen-limited, and that atmospheric nitrogen deposition has changed the balance of nitrogen and phosphorous in lakes.

Eutrophication effects from nitrogen deposition are most likely to be manifested in undisturbed, low nutrient surface waters such as those found in the higher elevation areas of the western United States. The most severe eutrophication from nitrogen deposition effects is expected downwind of major

urban and agricultural centers. High concentrations of lake or streamwater NO_3^- , indicative of ecosystem saturation, have been found at a variety of locations throughout the United States, including the San Bernardino and San Gabriel Mountains within the Los Angeles Air Basin, the Front Range of Colorado, the Allegheny mountains of West Virginia, the Catskill Mountains of New York, the Adirondack Mountains of New York, and the Great Smoky Mountains in Tennessee (U.S. EPA, 2008, section 3.3.8).

With regard to estuaries, the ISA concludes that the evidence is sufficient to infer a causal relationship between nitrogen deposition and the biogeochemical cycling of nitrogen and carbon in estuaries (U.S. EPA, 2008, section 4.3.4.1 and 3.3.2.3). In general, estuaries tend to be nitrogen-limited, and many currently receive high levels of nitrogen input from human activities (U.S. EPA, 2009, section 5.1.1). It is unknown if atmospheric deposition alone is sufficient to cause eutrophication; however, the contribution of atmospheric nitrogen deposition to total nitrogen load is calculated for some estuaries and can be >40 percent (U.S. EPA, 2009, section 5.1.1). The evidence is also sufficient to infer a causal relationship between nitrogen deposition and the alteration of species richness, species composition and biodiversity in estuarine ecosystems (U.S. EPA, 2008, section 4.3.4.2 and 3.3.5.4). Atmospheric and non-atmospheric sources of nitrogen contribute to increased phytoplankton and algal productivity, leading to eutrophication. Shifts in community composition, reduced hypolimnetic dissolved oxygen (DO), decreases in biodiversity, and mortality of submerged aquatic vegetation are associated with increased N deposition in estuarine systems.

In contrast to terrestrial and freshwater systems, atmospheric nitrogen load to estuaries contributes to the total load but does not necessarily drive the effects since other combined sources of nitrogen often greatly exceed nitrogen deposition. In estuaries, nitrogen-loading from multiple anthropogenic and non-anthropogenic pathways leads to water quality deterioration, resulting in numerous effects including hypoxic zones, species mortality, changes in community composition and harmful algal blooms that are indicative of eutrophication.

A recent national assessment of eutrophic conditions in estuaries found that 65 percent of the assessed systems had moderate to high overall eutrophic conditions. Most eutrophic estuaries

occurred in the mid-Atlantic region and the estuaries with the lowest degree of eutrophication were in the North Atlantic. Other regions had mixtures of low, moderate, and high degrees of eutrophication (U.S. EPA, 2008, section 4.3.4.3). The mid-Atlantic region is the most heavily impacted area in terms of moderate or high loss of submerged aquatic vegetation due to eutrophication (U.S. EPA, 2008, section 4.3.4.2). Submerged aquatic vegetation is important to the quality of estuarine ecosystem habitats because it provides habitat for a variety of aquatic organisms, absorbs excess nutrients, and traps sediments (U.S. EPA, 2008, section 4.3.4.2). It is partly because many estuaries and near-coastal marine waters are degraded by nutrient enrichment that they are highly sensitive to potential negative impacts from nitrogen addition from atmospheric deposition.

iii. Effects on Metal Toxicity

As discussed in the ISA (U.S. EPA, 2008, section 3.4.1 and 4.5), mercury is a highly neurotoxic contaminant that enters the food web as a methylated compound, methylmercury (MeHg). Mercury is principally methylated by sulfur-reducing bacteria and can be taken up by microorganisms, zooplankton and macroinvertebrates. The contaminant is concentrated in higher trophic levels, including fish eaten by humans. Experimental evidence has established that only inconsequential amounts of MeHg can be produced in the absence of sulfate. Once MeHg is present, other variables influence how much accumulates in fish, but elevated mercury levels in fish can only occur where substantial amounts of MeHg are present. Current evidence indicates that in watersheds where mercury is present, increased oxides of sulfur deposition very likely results in additional production of MeHg which leads to greater accumulation of MeHg concentrations in fish. With respect to sulfur deposition and mercury methylation, the final ISA determined that “[t]he evidence is sufficient to infer a causal relationship between sulfur deposition and increased mercury methylation in wetlands and aquatic environments.”

The production of meaningful amounts of MeHg requires the presence of SO_4^{2-} and mercury, and where mercury is present, increased availability of SO_4^{2-} results in increased production of MeHg. There is increasing evidence on the relationship between sulfur deposition and increased methylation of mercury in aquatic environments; this effect occurs only where other factors are present at levels

within a range to allow methylation. The production of MeHg requires the presence of SO_4^{2-} and mercury, but the amount of MeHg produced varies with oxygen content, temperature, pH, and supply of labile organic carbon (U.S. EPA, 2008, section 3.4). In watersheds where changes in sulfate deposition did not produce an effect, one or several of those interacting factors were not in the range required for meaningful methylation to occur (U.S. EPA, 2008, section 3.4). Watersheds with conditions known to be conducive to mercury methylation can be found in the northeastern United States and southeastern Canada.

While the ISA concluded that the evidence was sufficient to infer a causal relationship between sulfur deposition and increased MeHg production in wetlands and aquatic ecosystems, the REA concluded that there was insufficient evidence to quantify the relationship between sulfur deposition and MeHg production. Therefore, only a qualitative assessment was included in chapter 6 of the REA. As a result, the PA could not reach a conclusion as to the adequacy of the existing SO_2 standards in protecting against welfare effects associated with increased mercury methylation.

2. Overview of Risk and Exposure Assessment

The risk and exposure assessment conducted for the current review was developed to describe potential risk from current and future deposition of oxides of nitrogen and sulfur to sensitive ecosystems. The case study analyses in the REA show that there is confidence that known or anticipated adverse ecological effects are occurring under current ambient loadings of nitrogen and sulfur in sensitive ecosystems across the United States. An overview of the analytic approaches used in the REA, a summary of the key findings from the air quality analyses and acidification and nutrient enrichment case studies, and general conclusions regarding other welfare effects are presented below.

a. Approach to REA Analyses

The REA evaluates the relationships between atmospheric concentrations, deposition, biologically relevant exposures, targeted ecosystem effects, and ecosystem services. To evaluate the nature and magnitude of adverse effects associated with deposition, the REA also examines various ways to quantify the relationships between air quality indicators, deposition of biologically available forms of nitrogen and sulfur, ecologically relevant indicators relating

to deposition, exposure and effects on sensitive receptors, and related effects resulting in changes in ecosystem structure and services. The intent is to determine the exposure metrics that incorporate the temporal considerations (i.e., biologically relevant timescales), pathways, and ecologically relevant indicators necessary to determine the effects on these ecosystems. To the extent feasible, the REA evaluates the overall load to the system for nitrogen and sulfur, as well as the variability in ecosystem responses to these pollutants. It also evaluates the contributions of atmospherically deposited nitrogen and sulfur individually relative to the combined atmospheric loadings of both elements together. Since oxidized nitrogen is the listed criteria pollutant (currently measured by the ambient air quality indicator NO_2) for the atmospheric contribution to total nitrogen, the REA examines the contribution of nitrogen oxides to total reactive nitrogen in the atmosphere, relative to the contributions of reduced forms of nitrogen (e.g., ammonia, ammonium), to ultimately assess how a meaningful secondary NAAQS might be structured.

The REA focuses on ecosystem welfare effects that result from the deposition of total reactive nitrogen and sulfur. Because ecosystems are diverse in biota, climate, geochemistry, and hydrology, response to pollutant exposures can vary greatly between ecosystems. In addition, these diverse ecosystems are not distributed evenly across the United States. To target nitrogen and sulfur acidification and nitrogen and sulfur enrichment, the REA addresses four main targeted ecosystem effects on terrestrial and aquatic systems identified by the ISA (U.S. EPA, 2008): Aquatic acidification due to nitrogen and sulfur; terrestrial acidification due to nitrogen and sulfur; aquatic nutrient enrichment, including eutrophication; and terrestrial nutrient enrichment. In addition to these four targeted ecosystem effects, the REA also qualitatively addresses the influence of sulfur oxides deposition on MeHg production; nitrous oxide (N_2O) effects on climate; nitrogen effects on primary productivity and biogenic greenhouse gas (GHG) fluxes; and phytotoxic effects on plants.

Because the targeted ecosystem effects outlined above are not evenly distributed across the United States, the REA identified case studies for each targeted effects based on ecosystems identified as sensitive to nitrogen and/or sulfur deposition effects. Eight case study areas and two supplemental study areas (Rocky Mountain National Park

and Little Rock Lake, Wisconsin) are summarized in the REA based on ecosystem characteristics, indicators, and ecosystem service information. Case studies selected for aquatic acidification effects were the Adirondack Mountains and Shenandoah National Park. Kane Experimental Forest in Pennsylvania and Hubbard Brook Experimental Forest in New Hampshire were selected as case studies for terrestrial acidification. Aquatic nutrient enrichment case study locations were selected in the Potomac River Basin upstream of Chesapeake Bay and the Neuse River Basin upstream of the Pamlico Sound in North Carolina. The CSS communities in southern California and the mixed conifer forest (MCF) communities in the San Bernardino and Sierra Nevada Mountains of California were selected as case studies for terrestrial nutrient enrichment. Two supplemental areas were also chosen, one in Rocky Mountain National Park for terrestrial nutrient enrichment and one in Little Rock Lake, Wisconsin for aquatic nutrient enrichment.

For aquatic and terrestrial acidification effects, a similar conceptual approach was used (critical loads) to evaluate the impacts of multiple pollutants on an ecological endpoint, whereas the approaches used for aquatic and terrestrial nutrient enrichment were fundamentally distinct. Although the ecological indicators for aquatic and terrestrial acidification (i.e., ANC and BC/Al) are very different, both ecological indicators are well-correlated with effects such as reduced biodiversity and growth. While aquatic acidification is clearly the targeted effect area with the highest level of confidence, the relationship between atmospheric deposition and an ecological indicator is also quite strong for terrestrial acidification. The main drawback with the understanding of terrestrial acidification is that the data are based on laboratory responses rather than field measurements. Other stressors that are present in the field but that are not present in the laboratory may confound this relationship.

For nutrient enrichment effects, the REA utilized different types of indicators for aquatic and terrestrial effects to assess both the likelihood of adverse effects to ecosystems and the relationship between adverse effects and atmospheric sources of oxides of nitrogen. The ecological indicator chosen for aquatic nutrient enrichment, the Assessment of Estuarine Trophic Status Eutrophication Index (ASSETS EI), seems to be inadequate to relate atmospheric deposition to the targeted ecological effect, likely due to the many

other confounding factors. Further, there is far less confidence associated with the understanding of aquatic nutrient enrichment because of the large contributions from non-atmospheric sources of nitrogen and the influence of both oxidized and reduced forms of nitrogen, particularly in large watersheds and coastal areas. However, a strong relationship exists between atmospheric deposition of nitrogen and ecological effects in high alpine lakes in the Rocky Mountains because atmospheric deposition is the only source of nitrogen to these systems. There is also a strong weight-of-evidence regarding the relationships between ecological effects attributable to terrestrial nitrogen nutrient enrichment; however, ozone and climate change may be confounding factors. In addition, the response for other species or species in other regions of the United States has not been quantified.

b. Key Findings

In summary, based on case study analyses, the REA concludes that known or anticipated adverse ecological effects are occurring under current conditions and further concludes that these adverse effects continue into the future. Key findings from the air quality analyses, acidification and nutrient enrichment case studies, as well as general conclusions from evaluating additional welfare effects, are summarized below.

i. Air Quality Analyses

The air quality analyses in the REA encompass the current emissions sources of nitrogen and sulfur, as well as atmospheric concentrations, estimates of deposition of total nitrogen, policy-relevant background, and non-atmospheric loadings of nitrogen and sulfur to ecosystems, both nationwide and in the case study areas. Spatial fields of deposition were created using wet deposition measurements from the NADP National Trends Network and dry deposition predictions from the 2002 CMAQ model simulation. Some key conclusions from this analysis are:

(1) Total reactive nitrogen deposition and sulfur deposition are much greater in the East compared to most areas of the West.

(2) These regional differences in deposition correspond to the regional differences in oxides of nitrogen and SO_2 concentrations and emissions, which are also higher in the East. Oxides of nitrogen emissions are much greater and generally more widespread than ammonia (NH_3) emissions nationwide; high NH_3 emissions tend to be more local (e.g., eastern North Carolina) or sub-regional (e.g., the upper

Midwest and Plains states). The relative amounts of oxidized versus reduced nitrogen deposition are consistent with the relative amounts of oxides of nitrogen and NH_3 emissions. Oxidized nitrogen deposition exceeds reduced nitrogen deposition in most of the case study areas; the major exception being the Neuse River/Neuse River Estuary Case Study Area.

(3) Reduced nitrogen deposition exceeds oxidized nitrogen deposition in the vicinity of local sources of NH_3 .

(4) There can be relatively large spatial variations in both total reactive nitrogen deposition and sulfur deposition within a case study area; this occurs particularly in those areas that contain or are near a high emissions source of oxides of nitrogen, NH_3 and/or SO_2 .

(5) The seasonal patterns in deposition differ between the case study areas. For the case study areas in the East, the season with the greatest amounts of total reactive nitrogen deposition correspond to the season with the greatest amounts of sulfur deposition. Deposition peaks in spring in the Adirondack, Hubbard Brook Experimental Forest, and Kane Experimental Forest case study areas, and it peaks in summer in the Potomac River/Potomac Estuary, Shenandoah, and Neuse River/Neuse River Estuary case study areas. For the case study areas in the West, there is less consistency in the seasons with greatest total reactive nitrogen and sulfur deposition in a given area. In general, both nitrogen and/or sulfur deposition peaks in spring or summer. The exception to this is the Sierra Nevada Range portion of the MCF Case Study Area, in which sulfur deposition is greatest in winter.

ii. Aquatic Acidification Case Studies

The role of aquatic acidification in two eastern United States areas—northeastern New York's Adirondack area and the Shenandoah area in Virginia—was analyzed in the REA to assess surface water trends in SO_4^{2-} and NO_3^- concentrations and ANC levels and to affirm the understanding that reductions in deposition could influence the risk of acidification. Monitoring data from the EPA-administered Temporally Integrated Monitoring of Ecosystems/Long-Term Monitoring (TIME/LTM) programs and the Environmental Monitoring and Assessment Program (EMAP) were assessed for the years 1990 to 2006, and past, present and future water quality levels were estimated using both steady-state and dynamic biogeochemical models.

Although wet deposition rates for SO_2 and oxides of nitrogen in the Adirondack Case Study Area have reduced since the mid-1990s, current concentrations are still well above pre-acidification (1860) conditions. For a discussion of the uncertainties of pre-acidification, see U.S. EPA, 2011, Appendix F. The Model of Acidification of Groundwater in Catchments (MAGIC) modeling predicts NO_3^- and SO_4^{2-} are 17- and 5-fold higher today, respectively. The estimated average ANC for 44 lakes in the Adirondack Case Study Area is 62.1 $\mu\text{eq/L}$ (± 15.7 $\mu\text{eq/L}$); 78 percent of all monitored lakes in the Adirondack Case Study Area have a current risk of Elevated, Severe, or Acute. Of the 78 percent, 31 percent experience episodic acidification, and 18 percent are chronically acidic today.

(1) Based on the steady-state critical load model for the year 2002, 18 percent, 28 percent, 44 percent, and 58 percent of 169 modeled lakes received combined total sulfur and nitrogen deposition that exceeded critical loads corresponding to ANC limits of 0, 20, 50, and 100 $\mu\text{eq/L}$ respectively.

(2) Based on a deposition scenario that maintains current emission levels to 2020 and 2050, the simulation forecast indicates no improvement in water quality in the Adirondack Case Study Area. The percentage of lakes within the Elevated to Acute Concern classes remains the same in 2020 and 2050.

(3) Since the mid-1990s, streams in the Shenandoah Case Study Area have shown slight declines in NO_3^- and SO_4^{2-} concentrations in surface waters. The ANC levels increased from about 50 $\mu\text{eq/L}$ in the early 1990s to >75 $\mu\text{eq/L}$ until 2002, when ANC levels declined back to 1991–1992 levels. Current concentrations are still above pre-acidification (1860) conditions. The MAGIC modeling predicts surface water concentrations of NO_3^- and SO_4^{2-} are 10- and 32-fold higher today, respectively. The estimated average ANC for 60 streams in the Shenandoah Case Study Area is 57.9 $\mu\text{eq/L}$ (± 4.5 $\mu\text{eq/L}$). Fifty-five percent of all monitored streams in the Shenandoah Case Study Area have a current risk of Elevated, Severe, or Acute. Of the 55 percent, 18 percent experience episodic acidification, and 18 percent are chronically acidic today.

(4) Based on the steady-state critical load model for the year 2002, 52 percent, 72 percent, 85 percent and 93 percent of 60 modeled streams received combined total sulfur and nitrogen deposition that exceeded critical loads corresponding to ANC limits of 0, 20, 50, and 100 $\mu\text{eq/L}$ respectively.

(5) Based on a deposition scenario that maintains current emission levels to 2020 and 2050, the simulation forecast indicates that a large number of streams would still have Elevated to Acute problems with acidity.

iii. Terrestrial Acidification Case Studies

The role of terrestrial acidification was examined in the REA using a critical load analysis for sugar maple and red spruce forests in the eastern United States by using the BC/Al ratio in acidified forest soils as an indicator to assess the impact of nitrogen and sulfur deposition on tree health. These are the two most commonly studied species in North America for impacts of acidification. At a BC/Al ratio of 1.2, red spruce growth can be reduced by 20 percent. Sugar maple growth can be reduced by 20 percent at a BC/Al ratio of 0.6. Key findings of the case study are summarized below.

(1) Case study results suggest that the health of at least a portion of the sugar maple and red spruce growing in the United States may have been compromised with acidifying total nitrogen and sulfur deposition in 2002. The 2002 CMAQ/NADP total nitrogen and sulfur deposition levels exceeded three selected critical loads in 3 percent to 75 percent of all sugar maple plots across 24 states. The three critical loads ranged from 6,008 to 107 eq/ha/yr for the BC/Al ratios of 0.6, 1.2, and 10.0 (increasing levels of tree protection). The 2002 CMAQ/NADP total nitrogen and sulfur deposition levels exceeded three selected critical loads in 3 percent to 36 percent of all red spruce plots across eight states. The three critical loads ranged from 4,278 to 180 eq/ha/yr for the BC/Al ratios of 0.6, 1.2, and 10.0 (increasing levels of tree protection).

(2) The SMB model assumptions made for base cation weathering (Bcw) and forest soil ANC input parameters are the main sources of uncertainty since these parameters are rarely measured and require researchers to use default values.

(3) The pattern of case study results suggests that nitrogen and sulfur acidifying deposition in the sugar maple and red spruce forest areas studied were similar in magnitude to the critical loads for those areas and both ecosystems are likely to be sensitive to any future changes in the levels of deposition.

iv. Aquatic Nutrient Enrichment Case Studies

The role of nitrogen deposition in two main stem rivers feeding their respective estuaries was analyzed in the REA to determine if decreases in deposition could influence the risk of eutrophication as predicted using the ASSETS EI scoring system in tandem with SPARROW (SPATIally Referenced Regression on Watershed Attributes) modeling. This modeling approach provides a transferrable, intermediate-level analysis of the linkages between atmospheric deposition and receiving waters, while providing results on which conclusions could be drawn. A summary of findings follows:

(1) The 2002 CMAQ/NADP results showed that an estimated 40,770,000 kilograms (kg) of total nitrogen was deposited in the Potomac River watershed. The SPARROW modeling predicted that 7,380,000 kg N/yr of the deposited nitrogen reached the estuary (20 percent of the total load to the estuary). The overall ASSETS EI for the Potomac River and Potomac Estuary was Bad (based on all sources of N).

(2) To improve the Potomac River and Potomac Estuary ASSETS EI score from Bad to Poor, a decrease of at least 78 percent in the 2002 total nitrogen atmospheric deposition load to the watershed would be required.

(3) The 2002 CMAQ/NADP results showed that an estimated 18,340,000 kg of total nitrogen was deposited in the Neuse River watershed. The SPARROW modeling predicted that 1,150,000 kg N/yr of the deposited nitrogen reached the estuary (26 percent of the total load to the estuary). The overall ASSETS EI for the Neuse River/Neuse River Estuary was Bad.

(4) It was found that the Neuse River/Neuse River Estuary ASSETS EI score could not be improved from Bad to Poor with decreases only in the 2002 atmospheric deposition load to the watershed. Additional reductions would be required from other nitrogen sources within the watershed.

The small effect of decreasing atmospheric deposition in the Neuse River watershed is because the other nitrogen sources within the watershed are more influential than atmospheric deposition in affecting the total nitrogen loadings to the Neuse River Estuary, as estimated with the SPARROW model. A water body's response to nutrient loading depends on the magnitude (e.g., agricultural sources have a higher influence in the Neuse than in the Potomac), spatial distribution, and other characteristics of the sources within the watershed; therefore a reduction in

nitrogen deposition does not always produce a linear response in reduced load to the estuary, as demonstrated by these two case studies.

v. Terrestrial Nutrient Enrichment Case Studies

California CSS and MCF communities were the focus of the Terrestrial Nutrient Enrichment Case Studies of the REA. Geographic information systems analysis supported a qualitative review of past field research to identify ecological benchmarks associated with CSS and mycorrhizal communities, as well as MCF's nutrient-sensitive acidophyte lichen communities, fine-root biomass in Ponderosa pine and leached nitrate in receiving waters. These benchmarks, ranging from 3.1 to 17 kg N/ha/yr, were compared to 2002 CMAQ/NADP data to discern any associations between atmospheric deposition and changing communities. Evidence supports the finding that nitrogen alters CSS and MCF. Key findings include the following:

(1) The 2002 CMAQ/NADP nitrogen deposition data show that the 3.3 kg N/ha/yr benchmark has been exceeded in more than 93 percent of CSS areas (654,048 ha). This suggests that such deposition is a driving force in the degradation of CSS communities. One potentially confounding factor is the role of fire. Although CSS decline has been observed in the absence of fire, the contributions of deposition and fire to the CSS decline require further research. The CSS is fragmented into many small parcels, and the 2002 CMAQ/NADP 12-km grid data are not fine enough to fully validate the relationship between CSS distribution, nitrogen deposition, and fire.

(2) The 2002 CMAQ/NADP nitrogen deposition data exceeds the 3.1 kg N/ha/yr benchmark in more than 38 percent (1,099,133 ha) of MCF areas, and nitrate leaching has been observed in surface waters. Ozone effects confound nitrogen effects on MCF acidophyte lichen, and the interrelationship between fire and nitrogen cycling requires additional research.

c. Other Welfare Effects

Ecological effects have also been documented across the United States where elevated nitrogen deposition has been observed, including the eastern slope of the Rocky Mountains where shifts in dominant algal species in alpine lakes have occurred where wet nitrogen deposition was only about 1.5 kg N/ha/yr. High alpine terrestrial communities have a low capacity to sequester nitrogen deposition, and monitored deposition exceeding 3 to 4

kg N/ha/yr could lead to community-level changes in plant species, lichens and mycorrhizae.

Additional welfare effects are documented, but examined less extensively, in the REA. These effects include qualitative discussions related to visibility and materials damage, such as corrosion, erosion, and soiling of paint and buildings which are being addressed in the PM NAAQS review currently underway. A discussion of the causal relationship between sulfur deposition (as sulfate, SO_4^{2-}) and increased mercury methylation in wetlands and aquatic environments is also included in the REA. On this subject the REA concludes that decreases in SO_4^{2-} deposition will likely result in decreases in MeHg concentration; however, spatial and biogeochemical variations nationally hinder establishing large scale dose-response relationships.

Several additional issues concerning oxides of nitrogen were addressed in the REA. Consideration was also given to N_2O , a potent GHG. The REA concluded that it is most appropriate to analyze the role of N_2O in the context of all of the GHGs rather than as part of the REA for this review. The REA considered nitrogen deposition and its correlation with the rate of photosynthesis and net primary productivity. Nitrogen addition ranging from 15.4 to 300 kg N/ha/yr is documented as increasing wetland N_2O production by an average of 207 percent across all ecosystems. Nitrogen addition ranging from 30 to 240 kg N/ha/yr increased methane (CH_4) emissions by 115 percent, averaged across all ecosystems, and methane uptake was reduced by 38 percent averaged across all ecosystems when nitrogen addition ranged from 10 to 560 kg N/ha/yr, but reductions were only significant for coniferous and deciduous forests. The heterogeneity of ecosystems across the United States, however, introduces variations into dose-response relationships.

The phytotoxic effects of oxides of nitrogen and sulfur on vegetation were also briefly discussed in the REA which concluded that since a unique secondary NAAQS exists for SO_2 , and concentrations of nitric oxide (NO), NO_2 and PAN are rarely high enough to have phytotoxic effects on vegetation, further assessment was not warranted at this time.

3. Overview of Adversity of Effects to Public Welfare

Characterizing a known or anticipated adverse effect to public welfare is an important component of developing any secondary NAAQS. According to the

CAA, welfare effects include: “effects on soils, water, crops, vegetation, manmade materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effect on economic values and on personal comfort and well-being, whether caused by transformation, conversion, or combination with other air pollutants” (CAA, Section 302(h)). While the text above lists a number of welfare effects, these effects do not define public welfare in and of themselves.

Although there is no specific definition of adversity to public welfare, the paradigm of linking adversity to public welfare to disruptions in ecosystem structure and function has been used broadly by the EPA to categorize effects of pollutants from the cellular to the ecosystem level. An evaluation of adversity to public welfare might consider the likelihood, type, magnitude, and spatial scale of the effect as well as the potential for recovery and any uncertainties relating to these considerations.

Similar concepts were used in past reviews of secondary NAAQS for ozone and PM (relating to visibility), as well as in initial reviews of effects from lead deposition. Because oxides of nitrogen and sulfur are deposited from ambient sources into ecosystems where they affect changes to organisms, populations and ecosystems, the concept of adversity to public welfare as a result of alterations in structure and function of ecosystems is an appropriate consideration for this review.

Based on information provided in the PA, the following section discusses how ecological effects from deposition of oxides of nitrogen and sulfur relate to adversity to public welfare. In the PA, public welfare was discussed in terms of loss of ecosystem services (defined below), which in some cases can be monetized. Each of the four main effect areas (aquatic and terrestrial acidification and aquatic and terrestrial nutrient over-enrichment) are discussed including current ecological effects and associated ecosystem services.

a. Ecosystem Services

The PA defines ecosystem services as the benefits individuals and organizations obtain from ecosystems. Ecosystem services can be classified as provisioning (food and water), regulating (control of climate and disease), cultural (recreational, existence, spiritual, educational), and supporting (nutrient cycling). Conceptually, changes in ecosystem services may be used to aid in characterizing a known or anticipated

adverse effect to public welfare. In the REA and PA ecosystem services are discussed as a method of assessing the magnitude and significance to the public of resources affected by ambient concentrations of oxides of nitrogen and sulfur and deposition in sensitive ecosystems.

The EPA has in previous NAAQS reviews defined ecological goods and services for the purposes of a Regulatory Impact Analysis (RIA) as the “outputs of ecological functions or processes that directly or indirectly contribute to social welfare or have the potential to do so in the future. Some outputs may be bought and sold, but most are not marketed.” It is especially important to acknowledge that it is difficult to measure and/or monetize the goods and services supplied by ecosystems. It can be informative in characterizing adversity to public welfare to attempt to place an economic valuation on the set of goods and services that have been identified with respect to a change in policy however it must be noted that this valuation will be incomplete and illustrative only.

Knowledge about the relationships linking ambient concentrations and ecosystem services is considered in the PA as one method by which to inform a policy judgment on a known or anticipated adverse public welfare effect. For example, a change in an ecosystem structure and process, such as foliar injury, would be classified as an ecological effect, with the associated changes in ecosystem services, such as primary productivity, food availability, forest products, and aesthetics (e.g., scenic viewing), classified as public welfare effects. Additionally, changes in biodiversity would be classified as an ecological effect, and the associated changes in ecosystem services—productivity, existence (nonuse) value, recreational viewing and aesthetics—would also be classified as public welfare effects.

As described in chapters 4 and 5 of the REA, case study analyses were performed that link deposition in sensitive ecosystems to changes in a given ecological indicator (e.g., for aquatic acidification, to changes in ANC) and then to changes in ecosystems. Appendix 8 of the REA links the changes in ecosystems to the services they provide (e.g., fish species richness and its influence on recreational fishing). To the extent possible for each targeted effect area, the REA linked ambient concentrations of nitrogen and sulfur (i.e., ambient air quality indicators) to deposition in sensitive ecosystems (i.e., exposure pathways), and then to system response

as measured by a given ecological indicator (e.g., lake and stream acidification as measured by ANC). The ecological effect (e.g., changes in fish species richness) was then, where possible, associated with changes in ecosystem services and the corresponding public welfare effects (e.g., recreational fishing).

b. Effects on Ecosystem Services

The process used to link ecological indicators to ecosystem services is discussed extensively in appendix 8 of the REA. In brief, for each case study area assessed, the ecological indicators are linked to an ecological response that is subsequently linked to associated services to the extent possible. For example, in the case study for aquatic acidification the chosen ecological indicator is ANC which can be linked to the ecosystem service of recreational fishing. Although recreational fishing losses are the only service effects that can be independently quantified or monetized at this time, there are numerous other ecosystem services that may be related to the ecological effects of acidification.

While aquatic acidification is the focus of this proposed standard, the other effect areas were also analyzed in the REA and these ecosystems are being harmed by nitrogen and sulfur deposition and will obtain some measure of protection with any decrease in that deposition regardless of the reason for the decrease. The following summarizes the current levels of specific ecosystem services for aquatic and terrestrial acidification and aquatic and terrestrial nutrient over-enrichment and attempts to quantify and when possible monetize the harm to public welfare, as represented by ecosystem services, due to nitrogen and sulfur deposition.

i. Aquatic Acidification

Acidification of aquatic ecosystems primarily affects the ecosystem services that are derived from the fish and other aquatic life found in surface waters. In the northeastern United States, the surface waters affected by acidification are not a major source of commercially raised or caught fish; however, they are a source of food for some recreational and subsistence fishers and for other consumers. Although data and models are available for examining the effects on recreational fishing, relatively little data are available for measuring the effects on subsistence and other consumers. Inland waters also provide aesthetic and educational services along with non-use services, such as existence value (protection and preservation with

no expectation of direct use). In general, inland surface waters such as lakes, rivers, and streams also provide a number of regulating services, playing a role in hydrological regimes and climate regulation. There is little evidence that acidification of freshwaters in the northeastern United States has significantly degraded these specific services; however, freshwater ecosystems also provide biological control services by providing environments that sustain delicate aquatic food chains. The toxic effects of acidification on fish and other aquatic life impair these services by disrupting the trophic structure of surface waters. Although it is difficult to quantify these services and how they are affected by acidification, it is worth noting that some of these services may be captured through measures of provisioning and cultural services. For example, these biological control services may serve as “intermediate” inputs that support the production of “final” recreational fishing and other cultural services.

As summarized in Chapter 4 of the PA, recent studies indicate that acidification of lakes and streams can result in significant loss in economic value. Embedded in these numbers is a degree of harm to recreational fishing services due to acidification that has occurred over time. These harms have not been quantified on a regional scale; however, a case study was conducted in the Adirondacks area (U.S. EPA, 2011, section 4.4.2).

In the Adirondacks case study, estimates of changes in recreational fishing services were determined, as well as changes more broadly in “cultural” ecosystem services (including recreational, aesthetic, and nonuse services). First, the MAGIC model (U.S. EPA, 2009, Appendix 8 and section 2.2) was applied to 44 lakes to predict what ANC levels would be under both “business as usual” conditions (i.e., allowing for some decline in deposition due to existing regulations) and pre-emission (i.e., background) conditions. Second, to estimate the recreational fishing impacts of aquatic acidification in these lakes, an existing model of recreational fishing demand and site choice was applied. This model predicts how recreational fishing patterns in the Adirondacks would differ and how much higher the average annual value of recreational fishing services would be for New York residents if lake ANC levels corresponded to background (rather than business as usual) conditions. To estimate impacts on a broader category of cultural (and some provisioning) ecosystem services, results from the

Banzhaf et al (2006) valuation survey of New York residents were adapted and applied to this context. The focus of the survey was on impacts on aquatic resources. Pretesting of the survey indicated that respondents nonetheless tended to assume that benefits would occur in the condition of birds and forests as well as in recreational fishing.

The REA estimated 44 percent of the Adirondack lakes currently fall below an ANC of 50 $\mu\text{eq/L}$. Several states have set goals for improving the acid status of lakes and streams, generally targeting ANC in the range of 50 to 60 $\mu\text{eq/L}$, and have engaged in costly activities to decrease acidification.

These results imply significant value to the public in addition to those derived from recreational fishing services. Note that the results are only applicable to improvements in the Adirondacks valued by residents of New York. If similar benefits exist in other acid-impacted areas, benefits for the nation as a whole could be substantial. The analysis provides results on only a subset of the impacts of acidification on ecosystem services and suggests that the overall impact on these services could be substantial.

ii. Terrestrial Acidification

Chapters 4.4.3 and 4.4.4 of the PA review several economic studies of areas sensitive to terrestrial acidification. Forests in the northeastern United States provide several important and valuable provisioning ecosystem services, which are reflected in the production and sales of tree products. Sugar maples are a particularly important commercial hardwood tree species in the United States, producing timber and maple syrup that provide hundreds of millions of dollars in economic value annually. Red spruce is also used in a variety of wood products and provides up to \$100 million in economic value annually. Although the data do not exist to directly link acidification damages to economic values of lost recreational ecosystem services in forests, these resources are valuable to the public. The EPA is not able to quantify at this time the specific effects on these values of acid deposition, or of any specific reductions in deposition, relative to the effects of many other factors that may affect them.

iii. Nutrient Enrichment

Chapters 4.4.5 and 4.4.6 of the PA summarize economic studies of east coast estuaries affected by nutrient over-enrichment or eutrophication. Estuaries in the eastern United States are important for fish and shellfish production. The estuaries are capable of

supporting large stocks of resident commercial species, and they serve as the breeding grounds and interim habitat for several migratory species. To provide an indication of the magnitude of provisioning services associated with coastal fisheries, from 2005 to 2007, the average value of total catch was \$1.5 billion per year in 15 East Coast states. Estuaries also provide an important and substantial variety of cultural ecosystem services, including water-based recreational and aesthetic services. For example, data indicate that 4.8 percent of the population in coastal states from North Carolina to Massachusetts participated in saltwater fishing, with a total of 26 million saltwater fishing days in 2006. Recreational participation estimates for 1999–2000 showed almost 6 million individuals participated in motor boating in coastal states from North Carolina to Massachusetts. The EPA is not able to quantify at this time the specific effects on these values of nitrogen deposition, or of any specific reductions in deposition, relative to the effects of many other factors that may affect them.

Terrestrial ecosystems can also suffer from nutrient over-enrichment. Each ecosystem is different in its composition of species and nutrient requirements. Changes to individual ecosystems from changes in nitrogen deposition can be hard to assess economically. Relative recreational values are often determined by public use information. Chapter 4.4.7 of the PA reviewed studies related to park use in California. Data from California State Parks indicate that in 2002, 68.7 percent of surveyed individuals participated in trail hiking for an average of 24.1 days per year. The EPA is not able to quantify at this time the specific effects on these values of nitrogen deposition, or of any specific reductions in deposition, relative to the effects of many other factors that may affect them.

The PA also identified fire regulation as a service that could be affected by nutrient over-enrichment of the CSS and MCF ecosystems by encouraging growth of more flammable grasses, increasing fuel loads, and altering the fire cycle. Over the 5-year period from 2004 to 2008, Southern California experienced, on average, over 4,000 fires per year, burning, on average, over 400,000 acres per year. It is not possible at this time to quantify the contribution of nitrogen deposition, among many other factors, to increased fire risk.

c. Summary

Adversity to public welfare can be understood by looking at how deposition of oxides of nitrogen and

sulfur affect the ecological functions of an ecosystem (see II.A.), and then understanding the ecosystem services that are degraded. The monetized value of the ecosystem services provided by ecosystems that are sensitive to deposition of oxides of nitrogen and sulfur are in the billions of dollars each year, though it is not possible to quantify or monetize at this time the effects on these values of nitrogen and sulfur deposition or of any changes in deposition that may result from new secondary standards. Many lakes and streams are known to be degraded by acidic deposition which affects recreational fishing and tourism. Forest growth is likely suffering from acidic deposition in sensitive areas affecting red spruce and sugar maple timber production, sugar maple syrup production, hiking, aesthetic enjoyment and tourism. Nitrogen deposition contributes significantly to eutrophication in many estuaries affecting fish production, swimming, boating, aesthetic enjoyment and tourism. Ecosystem services are likely affected by nutrient enrichment in many natural and scenic terrestrial areas, affecting biodiversity, including habitat for rare and endangered species, fire control, hiking, aesthetic enjoyment and tourism.

B. Adequacy of the Current Standards

An important issue to be addressed in this review of the secondary standards for oxides of nitrogen and sulfur is whether, in view of the scientific evidence reflected in the ISA, additional information on exposure and risk discussed in the REA, and conclusions drawn from the PA, the current standards provide adequate protection of public welfare. In this review, consideration is given to the adequacy of the current standards with regard to both the direct effects of exposure to gaseous oxides of nitrogen and sulfur on vegetation and on potentially adverse deposition-related effects on sensitive aquatic and terrestrial ecosystems. This section is drawn from section II.D of the proposal. The following discussion summarizes the considerations related to the adequacy of the standards as discussed in the PA (section II.B.1), CASAC's views on adequacy (section II.B.2), and the Administrator's proposed conclusions on the adequacy of the current standards.

1. Adequacy Considerations

This discussion is based on the information presented in the PA and includes considerations related to the adequacy of the current NO₂ and SO₂ secondary standards with regard to

direct effects (section II.B.1.a), as well as considerations related to both the appropriateness and the adequacy of protection of the current standards with regard to deposition-related effects (section II.B.1.b).

a. Adequacy of the Current Standards for Direct Effects

For oxides of nitrogen, the current secondary standard was set identical to the primary standard,³ i.e., an annual standard set for NO₂ to protect against adverse effects on vegetation from direct exposure to ambient oxides of nitrogen. For oxides of sulfur, the current secondary standard is a 3-hour standard intended to provide protection for plants from the direct foliar damage associated with atmospheric concentrations of SO₂. In considering the adequacy of these standards, it is appropriate to consider whether they are adequate to protect against the direct effects on vegetation resulting from exposure to ambient oxides of nitrogen and sulfur, which was the basis for initially setting the standards in 1971. The ISA concludes that there was sufficient evidence to infer a causal relationship between exposure to SO₂, NO, NO₂ and PAN and injury to vegetation. Additional research on acute foliar injury has been limited and there is no evidence to suggest foliar injury below the levels of the current secondary standards. Based on information in the ISA, the PA concludes that there is sufficient evidence to suggest that the levels of the current standards are likely adequate to protect against phytotoxic effects caused by direct gas-phase exposure.

b. Appropriateness and Adequacy of the Current Standards for Deposition-related Effects

This section addresses two concepts necessary to evaluate the current standards in the context of deposition-related effects. First, appropriateness of the current standards is considered with regard to indicator, form, level and averaging time. This discussion includes particular emphasis on the indicators and forms of the current standards and the degree to which they are ecologically relevant with regard to deposition-related effects that vary spatially and temporally. Second, this section considers the current standards in terms of adequacy of protection.

³ The current primary NO₂ standard has recently been changed to the 3-year average of the 98th percentile of the annual distribution of the 1 hour daily maximum of the concentration of NO₂. The current secondary standard remains as it was set in 1971.

i. Appropriateness

The ISA has established that the major effects of concern for this review are associated with deposition of nitrogen and sulfur caused by atmospheric concentrations of oxides of nitrogen and sulfur. As discussed below, the current standards are not directed toward depositional effects, and none of the elements of the current NAAQS—indicator, form, averaging time, and level—are suited for addressing the effects of nitrogen and sulfur deposition.

Four issues arise that call into question the ecological relevance of the structure of the current secondary standards for oxides of nitrogen and sulfur.

(1) The current SO₂ secondary standard (0.5 ppm SO₂ over a 3-hour average) does not utilize an averaging time that relates to an exposure period that is relevant for ecosystem impacts. The majority of deposition-related impacts are associated with depositional loads that occur over periods of months to years. This differs significantly from exposures associated with hourly concentrations of SO₂ as measured by the current secondary standard. By addressing short-term concentrations, the current SO₂ secondary standard, while protective against direct foliar effects from gaseous oxides of sulfur, does not take into account the findings of effects in the ISA, which notes the relationship between annual deposition of sulfur and acidification effects which are likely to be more severe and widespread than phytotoxic effects under current ambient conditions, and include effects from long-term and short-term deposition. Acidification is a process that occurs over time because the ability of an aquatic system to counteract acidic inputs is reduced as natural buffers are used more rapidly than they can be replaced through geologic weathering. The relevant period of exposure for ecosystems is, therefore, not the exposures captured in the short averaging time of the current SO₂ secondary standard. The current secondary standard for oxides of nitrogen is an annual standard (0.053 ppm averaged over 1 year) and as such the averaging time of the standard is more ecologically relevant.

(2) Current standards do not utilize appropriate atmospheric indicators. Nitrogen dioxide and SO₂ are used as the species of oxides of nitrogen and sulfur that are measured to determine compliance with the standards, but they do not capture all relevant chemical species of oxides of nitrogen and sulfur that contribute to deposition-related

effects. The ISA provides evidence that deposition-related effects are associated with *total* nitrogen and *total* sulfur deposition, and thus all chemical species of oxidized nitrogen and oxidized sulfur that are deposited will contribute to effects on ecosystems. Thus, by using atmospheric NO₂ and SO₂ concentrations as indicators, the current standards address only a fraction of total atmospheric oxides of nitrogen and sulfur, and do not take into account the effects from deposition of total atmospheric oxides of nitrogen and sulfur. This suggests that more comprehensive atmospheric indicators should be considered in designing ecologically relevant standards.

(3) Current standards reflect separate assessments of the two individual pollutants, NO₂ and SO₂, rather than assessing the joint impacts of deposition of nitrogen and sulfur to ecosystems. Recognizing the role that each pollutant plays in jointly affecting ecosystem indicators, functions, and services is vital to developing a meaningful standard. The clearest example of this interaction is in assessment of the impacts of acidifying deposition on aquatic ecosystems. Acidification in an aquatic ecosystem depends on the total acidifying potential of the nitrogen and sulfur deposition resulting from oxides of nitrogen and sulfur as well as the inputs from other sources of nitrogen and sulfur such as reduced nitrogen and non-atmospheric sources. It is the joint impact of the two pollutants that determines the ultimate effect on organisms within the ecosystem, and critical ecosystem functions such as habitat provision and biodiversity. Standards that are set independently are less able to account for the contribution of the other pollutant. This suggests that interactions between oxides of nitrogen and oxides of sulfur should be a critical element of the conceptual framework for ecologically relevant standards. There are also important interactions between oxides of nitrogen and sulfur and reduced forms of nitrogen, which also contribute to acidification and nutrient enrichment. It is important that the structure of the standards address the role of reduced nitrogen in determining the ecological effects resulting from deposition of atmospheric oxides of nitrogen and sulfur. Consideration will also have to be given to total loadings as ecosystems respond to all sources of nitrogen and sulfur.

(4) Current standards do not take into account variability in ecosystem sensitivity. Ecosystems are not uniformly distributed either spatially or temporally in their sensitivity to oxides of nitrogen and sulfur. Therefore, failure

to account for the major determinants of variability, including geological and soil characteristics related to the sensitivity to acidification or nutrient enrichment, as well as atmospheric and landscape characteristics that govern rates of deposition, may lead to standards that do not provide requisite levels of protection across ecosystems. The current structures of the standards do not address the complexities in the responses of ecosystems to deposition of oxides of nitrogen and sulfur.

Ecosystems contain complex groupings of organisms that respond in various ways to the alterations of soil and water that result from deposition of nitrogen and sulfur compounds. Different ecosystems therefore respond depending on a multitude of factors that control how deposition is integrated into the system. For example, the same levels of deposition falling on limestone dominated soils have a very different effect from those falling on shallow glaciated soils underlain with granite. One system may over time display no obvious detriment while the other may experience a catastrophic loss in fish communities. This degree of sensitivity is a function of many atmospheric factors that control rates of deposition as well as ecological factors that control how an ecosystem responds to that deposition. The current standards do not take into account spatial and seasonal variations, not only in depositional loadings, but also in sensitivity of ecosystems exposed to those loadings. Based on the discussion summarized above, the PA concludes that the current secondary standards for oxides of nitrogen and oxides of sulfur are not ecologically relevant in terms of averaging time, form, level or indicator.

ii. Adequacy of Protection

As described in the PA, ambient conditions in 2005 indicate that the current SO₂ and NO₂ secondary standards were not exceeded at that time (U.S. EPA, 2011, Figures 6–1 and 6–2) in locations where negative ecological effects have been observed. In many locations, SO₂ and NO₂ concentrations are substantially below the levels of the secondary standards. This pattern suggests that levels of deposition and any negative effects on ecosystems due to deposition of oxides of nitrogen and sulfur under recent conditions are occurring even though areas meet or are below current standards. In addition, based on conclusions in the REA, these levels will not decline in the future to levels below which it is reasonable to anticipate effects.

In determining the adequacy of the current secondary standards for oxides of nitrogen and sulfur the PA considered the extent to which ambient deposition contributes to loadings in ecosystems. Since the last review of the secondary standard for oxides of nitrogen, a great deal of information on the contribution of atmospheric deposition associated with ambient oxides of nitrogen has become available. The REA presents a thorough assessment of the contribution of oxidized nitrogen relative to total nitrogen deposition throughout the United States, and the relative contributions of ambient oxidized and reduced forms of nitrogen. The REA concludes that based on that analysis, ambient oxides of nitrogen are a significant component of atmospheric nitrogen deposition, even in areas with relatively high rates of reduced nitrogen deposition. In addition, atmospheric deposition of oxidized nitrogen contributes significantly to total nitrogen loadings in nitrogen sensitive ecosystems.

The ISA summarizes the available studies of relative nitrogen contribution and finds that in much of the United States, oxides of nitrogen contribute from 50 to 75 percent of total atmospheric deposition relative to total reactive nitrogen, which includes oxidized and reduced nitrogen species (U.S. EPA, 2008, section 2.8.4). Although the proportion of total nitrogen loadings associated with atmospheric deposition of nitrogen varies across locations, the ISA indicates that atmospheric nitrogen deposition is the main source of new anthropogenic nitrogen to most headwater streams, high elevation lakes, and low-order streams. Atmospheric nitrogen deposition contributes to the total nitrogen load in terrestrial, wetland, freshwater and estuarine ecosystems that receive nitrogen through multiple pathways. In several large estuarine systems, including the Chesapeake Bay, atmospheric deposition accounts for between 10 and 40 percent of total nitrogen loadings (U.S. EPA, 2008).

Atmospheric concentrations of oxides of sulfur account for nearly all sulfur deposition in the U.S. For the period 2004–2006, mean sulfur deposition in the United States was greatest east of the Mississippi River with the highest deposition amount, 21.3 kg S/ha-yr, in the Ohio River Valley where most recording stations reported 3-year averages >10 kg S/ha-yr. Numerous other stations in the East reported S deposition >5 kg S/ha-yr. Total sulfur deposition in the United States west of

the 100th meridian was relatively low, with all recording stations reporting <2 kg S/ha-yr and many reporting <1 kg S/ha-yr. Sulfur was primarily deposited in the form of wet SO_4^{2-} followed in decreasing order by a smaller proportion of dry SO_2 and a much smaller proportion of deposition as dry SO_4^{2-} .

As discussed throughout the REA (U.S. EPA, 2009 and section II.B above), there are several key areas of risk that are associated with ambient concentrations of oxides of nitrogen and sulfur. As noted earlier, in previous reviews of the secondary standards for oxides of nitrogen and sulfur, the standards were designed to protect against direct exposure of plants to ambient concentrations of the pollutants. A significant shift in understanding of the effects of oxides of nitrogen and sulfur has occurred since the last reviews, reflecting the large amount of research that has been conducted on the effects of deposition of nitrogen and sulfur to ecosystems. The most significant current risks of adverse effects to public welfare are those related to deposition of oxides of nitrogen and sulfur to both terrestrial and aquatic ecosystems. These risks fall into two categories, acidification and nutrient enrichment, which were emphasized in the REA as most relevant to evaluating the adequacy of the existing standards in protecting public welfare from adverse ecological effects.

(a) Aquatic Acidification

The focus of the REA case studies was to determine whether deposition of sulfur and oxidized nitrogen in locations where ambient oxides of nitrogen and sulfur were at or below the current standards resulted in acidification and related effects, including episodic acidification and mercury methylation. Based on the case studies conducted for lakes in the Adirondacks and streams in Shenandoah National Park (case studies are discussed more fully in section II.B and U.S. EPA, 2009), there is significant risk to acid sensitive aquatic ecosystems at atmospheric concentrations of oxides of nitrogen and sulfur at or below the current standards. The REA also strongly supports a relationship between atmospheric deposition of oxides of nitrogen and sulfur and loss of ANC in sensitive ecosystems and indicates that ANC is an excellent indicator of aquatic acidification. The REA also concludes that at levels of deposition associated with oxides of nitrogen and sulfur concentrations at or below the current standards, ANC levels are expected to be below benchmark values that are associated with

significant losses in fish species richness.

Significant portions of the United States are acid sensitive, and current deposition levels exceed those that would allow recovery of the most acid sensitive lakes in the Adirondacks (U.S. EPA, 2008, Executive Summary). In addition, because of past loadings, areas of the Shenandoah are sensitive to current deposition levels (U.S. EPA, 2008, Executive Summary). Parts of the West are naturally less sensitive to acidification and subjected to lower deposition (particularly oxides of sulfur) levels relative to the eastern United States, and as such, less focus in the ISA is placed on the adequacy of the existing standards in these areas, with the exception of the mountainous areas of the West, which experience episodic acidification due to deposition.

In describing the effects of acidification in the two case study areas the REA uses the approach of describing benchmarks in terms of ANC values. Many locations in sensitive areas of the United States have ANC levels below benchmark levels for ANC classified as severe, elevated, or moderate concern (U.S. EPA, 2011, Figure 2–1). The average current ANC levels across 44 lakes in the Adirondack case study area is 62.1 $\mu\text{eq/L}$ (moderate concern). However, 44 percent of lakes had deposition levels exceeding the critical load for an ANC of 50 $\mu\text{eq/L}$ (elevated), and 28 percent of lakes had deposition levels exceeding the (higher) critical load for an ANC of 20 $\mu\text{eq/L}$ (severe) (U.S. EPA, 2009, section 4.2.4.2). This information indicates that almost half of the 44 lakes in the Adirondacks case study area are at an elevated concern level, and almost a third are at a severe concern level. These levels are associated with greatly diminished fish species diversity, and losses in the health and reproductive capacity of remaining populations. Based on assessments of the relationship between number of fish species and ANC level in both the Adirondacks and Shenandoah areas, the number of fish species is decreased by over half at an ANC level of 20 $\mu\text{eq/L}$ relative to an ANC level at 100 $\mu\text{eq/L}$ (U.S. EPA, 2009, Figure 4.2–1). When extrapolated to the full population of lakes in the Adirondacks area using weights based on the EMAP probability survey (U.S. EPA, 2009, section 4.2.6.1), 36 percent of lakes exceeded the critical load for an ANC of 50 $\mu\text{eq/L}$ and 13 percent of lakes exceeded the critical load for an ANC of 20 $\mu\text{eq/L}$.

Many streams in the Shenandoah case study area also have levels of deposition that are associated with ANC levels

classified as severe, elevated, or moderate concern. The average ANC under recent conditions for the 60 streams evaluated in the Shenandoah case study area is 57.9 $\mu\text{eq/L}$, indicating moderate concern. However, 85 percent of these streams had recent deposition exceeding the critical load for an ANC of 50 $\mu\text{eq/L}$, and 72 percent exceeded the critical load for an ANC of 20 $\mu\text{eq/L}$. As with the Adirondacks area, this information suggests that ANC levels may decline in the future and significant numbers of sensitive streams in the Shenandoah area are at risk of adverse impacts on fish populations if recent conditions persist. Many other streams in the Shenandoah area are also likely to experience conditions of elevated to severe concern based on the prevalence in the area of bedrock geology associated with increased sensitivity to acidification suggesting that effects due to stream acidification could be widespread in the Shenandoah area (U.S. EPA, 2009, section 4.2.6.2).

In addition to these chronic acidification effects, the ISA notes that “consideration of episodic acidification greatly increases the extent and degree of estimated effects for acidifying deposition on surface waters” (U.S. EPA, 2008, section 3.2.1.6). Some studies show that the number of lakes that could be classified as acid-impacted based on episodic acidification is 2 to 3 times the number of lakes classified as acid-impacted based on chronic ANC. These episodic acidification events can have long-term effects on fish populations (U.S. EPA, 2008, section 3.2.1.6). Under recent conditions, episodic acidification has been observed in locations in the eastern United States and in the mountainous western United States (U.S. EPA, 2008, section 3.2.1.6).

The ISA, REA and PA all conclude that the current standards are not adequate to protect against the adverse impacts of aquatic acidification on sensitive ecosystems. A recent survey, as reported in the ISA, found sensitive streams in many locations in the United States, including the Appalachian Mountains, the Coastal Plain, and the Mountainous West (U.S. EPA, 2008, section 4.2.2.3). In these sensitive areas, between 1 and 6 percent of stream kilometers are chronically acidified. The REA further concludes that both the Adirondack and Shenandoah case study areas are currently receiving deposition from ambient oxides of nitrogen and sulfur in excess of their ability to neutralize such inputs. In addition, based on the current emission scenarios, forecast modeling out to the year 2020 as well as 2050 indicates a large number of streams in these areas will still be

adversely impacted (section II.B). Based on these considerations, the PA concludes that the current secondary NAAQS for oxides of nitrogen and sulfur do not provide adequate protection of sensitive ecosystems with regard to aquatic acidification.

(b) Terrestrial Acidification

Based on the terrestrial acidification case studies, Kane Experimental Forest in Pennsylvania and Hubbard Brook Experimental Forest described in section II.B of sugar maple and red spruce habitat, the REA concludes that there is significant risk to sensitive terrestrial ecosystems from acidification at atmospheric concentrations of NO_2 and SO_2 at or below the current standards. The ecological indicator selected for terrestrial acidification is the BC/Al, which has been linked to tree health and growth. The results of the REA strongly support a relationship between atmospheric deposition of oxides of nitrogen and sulfur and BC/Al, and that BC/Al is a good indicator of terrestrial acidification. At levels of deposition associated with oxides of nitrogen and sulfur concentrations at or below the current standards, BC/Al levels are expected to be below benchmark values that are associated with significant effects on tree health and growth. Such degradation of terrestrial ecosystems could affect ecosystem services such as habitat provisioning, endangered species, goods production (timber, syrup, etc.) among others.

Many locations in sensitive areas of the United States have BC/Al levels below benchmark levels classified as providing low to intermediate levels of protection to tree health. At a BC/Al ratio of 1.2 (intermediate level of protection), red spruce growth can be reduced by 20 percent. At a BC/Al ratio of 0.6 (low level of protection), sugar maple growth can be decreased by 20 percent. The REA did not evaluate broad sensitive regions. However, in the sugar maple case study area (Kane Experimental Forest), recent deposition levels are associated with a BC/Al ratio below 1.2, indicating between intermediate and low level of protection, which would indicate the potential for a greater than 20 percent reduction in growth. In the red spruce case study area (Hubbard Brook Experimental Forest), recent deposition levels are associated with a BC/Al ratio slightly above 1.2, indicating slightly better than an intermediate level of protection (U.S. EPA, 2009, section 4.3.5.1).

Over the full range of sugar maple, 12 percent of evaluated forest plots

exceeded the critical loads for a BC/Al ratio of 1.2, and 3 percent exceeded the critical load for a BC/Al ratio of 0.6. However, there was large variability across states. In New Jersey, 67 percent of plots exceeded the critical load for a BC/Al ratio of 1.2, while in several states on the outskirts of the range for sugar maple (e.g. Arkansas, Illinois) no plots exceeded the critical load for a BC/Al ratio of 1.2. For red spruce, overall 5 percent of plots exceeded the critical load for a BC/Al ratio of 1.2, and 3 percent exceeded the critical load for a BC/Al ratio of 0.6. In the major red spruce producing states (Maine, New Hampshire, and Vermont), critical loads for a BC/Al ratio of 1.2 were exceeded in 0.5, 38, and 6 percent of plots, respectively.

The ISA, REA and PA all conclude that the current standards are not adequate to protect against the adverse impacts of terrestrial acidification on sensitive ecosystems. As stated in the REA and PA, the main drawback, with the understanding of terrestrial acidification lies in the sparseness of available data by which we can predict critical loads and that the data are based on laboratory responses rather than field measurements. Other stressors that are present in the field but that are not present in the laboratory may confound this relationship. The REA does however, conclude that the case study results, when extended to a 27 state region, show that nitrogen and sulfur acidifying deposition in the sugar maple and red spruce forest areas caused the calculated Bc/Al ratio to fall below 1.2 (the intermediate level of protection) in 12 percent of the sugar maple plots and 5 percent of the red spruce plots; however, results from individual states ranged from 0 to 67 percent of the plots for sugar maple and 0 to 100 percent of the plots for red spruce.

(c) Terrestrial Nutrient Enrichment

Nutrient enrichment effects are due to nitrogen loadings from both atmospheric and non-atmospheric sources. Evaluation of nutrient enrichment effects requires an understanding that nutrient inputs are essential to ecosystem health and that specific long-term levels of nutrients in a system affect the types of species that occur over long periods of time. Short-term additions of nutrients can affect species competition, and even small additions of nitrogen in areas that are traditionally nutrient poor can have significant impacts on productivity as well as species composition. Most ecosystems in the United States are nitrogen-limited, so regional decreases in emissions and deposition of airborne

nitrogen compounds could lead to some decrease in growth of the vegetation that surrounds the targeted aquatic system but as discussed below evidence for this is mixed. Whether these changes in plant growth are seen as beneficial or adverse will depend on the nature of the ecosystem being assessed.

Information on the effects of changes in nitrogen deposition on forestlands and other terrestrial ecosystems is very limited. The multiplicity of factors affecting forests, including other potential stressors such as ozone, and limiting factors such as moisture and other nutrients, confound assessments of marginal changes in any one stressor or nutrient in forest ecosystems. The ISA notes that only a fraction of the deposited nitrogen is taken up by the forests, most of the nitrogen is retained in the soils (U.S. EPA, 2008, section 3.3.2.1). In addition, the ISA indicates that forest management practices can significantly affect the nitrogen cycling within a forest ecosystem, and as such, the response of managed forests to nitrogen deposition will be variable depending on the forest management practices employed in a given forest ecosystem (U.S. EPA, 2008, Annex C.6.3). Increases in the availability of nitrogen in nitrogen-limited forests via atmospheric deposition could increase forest production over large non-managed areas, but the evidence is mixed, with some studies showing increased production and other showing little effect on wood production (U.S. EPA, 2008, section 3.3.9). Because leaching of nitrate can promote cation losses, which in some cases create nutrient imbalances, slower growth and lessened disease and freezing tolerances for forest trees, the net effect of increased N on forests in the United States is uncertain (U.S. EPA, 2008, section 3.3.9).

The scientific literature has many examples of the deleterious effects caused by excessive nitrogen loadings to terrestrial systems. Several studies have set benchmark values for levels of N deposition at which scientifically adverse effects are known to occur. Large areas of the country appear to be experiencing deposition above these benchmarks. The ISA indicates studies that have found that at 3.1 kg N/ha/yr, the community of lichens begins to change from acidophytic to tolerant species; at 5.2 kg N/ha/yr, the typical dominance by acidophytic species no longer occurs; and at 10.2 kg N/ha/yr, acidophytic lichens are totally lost from the community. Additional studies in the Colorado Front Range of the Rocky Mountain National Park support these findings. These three values (3.1, 5.2,

and 10.2 kg/ha/yr) are one set of ecologically meaningful benchmarks for the mixed conifer forest (MCF) of the Pacific coast regions. Nearly all of the known sensitive communities receive total nitrogen deposition levels above the 3.1 N kg/ha/yr ecological benchmark according to the 12 km, 2002 CMAQ/NADP data, with the exception of the easternmost Sierra Nevadas. The MCFs in the southern portion of the Sierra Nevada forests and nearly all MCF communities in the San Bernardino forests receive total nitrogen deposition levels above the 5.2 N kg/ha/yr ecological benchmark.

Coastal Sage Scrub communities are also known to be sensitive to community shifts caused by excess nitrogen loadings. Studies have investigated the amount of nitrogen utilized by healthy and degraded CSS systems. In healthy stands, the authors estimated that 3.3 kg N/ha/yr was used for CSS plant growth. It is assumed that 3.3 kg N/ha/yr is near the point where nitrogen is no longer limiting in the CSS community and above which level community changes occur, including dominance by invasive species and loss of coastal sage scrub. Therefore, this amount can be considered an ecological benchmark for the CSS community. The majority of the known CSS range is currently receiving deposition in excess of this benchmark. Thus, the REA concludes that recent conditions where oxides of nitrogen ambient concentrations are at or below the current oxides of nitrogen secondary standards are not adequate to protect against anticipated adverse impacts from N nutrient enrichment in sensitive ecosystems.

(d) Aquatic Nutrient Enrichment

The REA aquatic nutrient enrichment case studies focused on coastal estuaries and revealed that while current ambient loadings of atmospheric oxides of nitrogen are contributing to the overall depositional loading of coastal estuaries, other non-atmospheric sources are contributing in far greater amounts in total, although atmospheric contributions are as large as some other individual source types. The ability of current data and models to characterize the incremental adverse impacts of nitrogen deposition is limited, both by the available ecological indicators, and by the inability to attribute specific effects to atmospheric sources of nitrogen. The REA case studies used ASSETS EI as the ecological indicator for aquatic nutrient enrichment. This index is a six level index characterizing overall eutrophication risk in a water body. This indicator is not sensitive to

changes in nitrogen deposition within a single level of the index. In addition, this type of indicator does not reflect the impact of nitrogen deposition in conjunction with other sources of nitrogen.

Based on the above considerations, the REA concludes that the ASSETS EI is not an appropriate ecological indicator for estuarine aquatic eutrophication and that additional analysis is required to develop an appropriate indicator for determining the appropriate levels of protection from N nutrient enrichment effects in estuaries related to deposition of oxides of nitrogen. As a result, the EPA is unable to make a determination as to the adequacy of the existing secondary oxides of nitrogen standard in protecting public welfare from nitrogen nutrient enrichment effects in estuarine aquatic ecosystems.

Additionally, nitrogen deposition can alter species composition and cause eutrophication in freshwater systems. In the Rocky Mountains, for example, deposition loads of 1.5 to 2 kg/ha/yr which are well within current ambient levels are known to cause changes in species composition in diatom communities indicating impaired water quality (U.S. EPA, 2008, section 3.3.5.3). This suggests that the existing secondary standard for oxides of nitrogen does not protect such ecosystems and their resulting services from impairment.

(e) Other Effects

An important consideration in looking at the effects of deposition of oxides of sulfur in aquatic ecosystems is the potential for production of MeHg, a neurotoxic contaminant. The production of meaningful amounts of MeHg requires the presence of SO_4^{2-} and mercury, and where mercury is present, increased availability of SO_4^{2-} results in increased production of MeHg. There is increasing evidence on the relationship between sulfur deposition and increased methylation of mercury in aquatic environments; this effect occurs only where other factors are present at levels within a range to allow methylation. The production of MeHg requires the presence of SO_4^{2-} and mercury, but the amount of MeHg produced varies with oxygen content, temperature, pH and supply of labile organic carbon (U.S. EPA, 2008, section 3.4). In watersheds where changes in sulfate deposition did not produce an effect, one or several of those interacting factors were not in the range required for meaningful methylation to occur (U.S. EPA, 2008, section 3.4). Watersheds with conditions known to

be conducive to mercury methylation can be found in the northeastern United States and southeastern Canada (U.S. EPA, 2009, section 6).

With respect to sulfur deposition and mercury methylation, the final ISA determined that "[t]he evidence is sufficient to infer a causal relationship between sulfur deposition and increased mercury methylation in wetlands and aquatic environments." However, the EPA did not conduct a quantitative assessment of the risks associated with increased mercury methylation under current conditions. As such, the EPA is unable to make a determination as to the adequacy of the existing SO_2 secondary standards in protecting against welfare effects associated with increased mercury methylation.

c. Summary of Adequacy Considerations

In summary, the PA concludes that currently available scientific evidence and assessments clearly call into question the adequacy of the current standards with regard to deposition-related effects on sensitive aquatic and terrestrial ecosystems, including acidification and nutrient enrichment. Further, the PA recognizes that the elements of the current standards—indicator, averaging time, level and form—are not ecologically relevant, and are thus not appropriate for standards designed to provide such protection. Thus, the PA concludes that consideration should be given to establishing a new ecologically relevant multi-pollutant, multimedia standard to provide appropriate protection from deposition-related ecological effects of oxides of nitrogen and sulfur on sensitive ecosystems, with a focus on protecting against adverse effects associated with acidifying deposition in sensitive aquatic ecosystems.

2. CASAC Views

In a letter to the Administrator (Russell and Samet 2011a), the CASAC Oxides of Nitrogen and Oxides of Sulfur Panel, with full endorsement of the chartered CASAC, unanimously concluded that:

"EPA staff has demonstrated through the Integrated Science Assessment (ISA), Risk and Exposure Characterization (REA) and the draft PA that ambient NO_x and SO_x can have, and are having, adverse environmental impacts. The Panel views that the current NO_x and SO_x secondary standards should be retained to protect against direct adverse impacts to vegetation from exposure to gas phase exposures of these two families of air pollutants. Further, the ISA, REA and draft PA demonstrate that adverse impacts to aquatic ecosystems are also occurring due to deposition of NO_x and SO_x . Those impacts

include acidification and undesirable levels of nutrient enrichment in some aquatic ecosystems. The levels of the current NO_x and SO_x secondary NAAQS are not sufficient, nor the forms of those standards appropriate, to protect against adverse depositional effects; thus a revised NAAQS is warranted.”

In addition, with regard to the joint consideration of both oxides of nitrogen and oxides of sulfur as well as the consideration of deposition-related effects, CASAC concluded that the PA had developed a credible methodology for considering such effects. The Panel stated that “the Policy Assessment develops a framework for a multi-pollutant, multimedia standard that is ecologically relevant and reflects the combined impacts of these two pollutants as they deposit to sensitive aquatic ecosystems.”

3. Administrator’s Proposed Conclusions

Based on the above considerations and taking into account CASAC advice, in the proposed rule the Administrator considered the adequacy of the current NO₂ and SO₂ secondary standards with regard to both direct effects on vegetation, as well as on deposition-related effects on sensitive ecosystems. With regard to direct phytotoxic effects on vegetation, the Administrator concluded that the current secondary standards are adequately protective, and thus proposed to retain the current NO₂ and SO₂ secondary standards for that purpose.

With regard to deposition-related effects, the Administrator first considered the appropriateness of the structure of the current standards to address ecological effects of concern. Based on the evidence as well as considering the advice given by CASAC, the Administrator concluded that the elements of the current standards are not ecologically relevant and thus are not appropriate to provide protection of ecosystems. In considering the adequacy of protection with regard to deposition-related effects, the Administrator considered the full nature of ecological effects related to the deposition of ambient oxides of nitrogen and sulfur into sensitive ecosystems across the country. Based on the evidence and information evaluated in the ISA, REA, and PA, and taking into account CASAC advice, the Administrator concluded that current levels of oxides of nitrogen and sulfur are sufficient to cause acidification of both aquatic and terrestrial ecosystems, nutrient enrichment of terrestrial ecosystems and contribute to nutrient enrichment effects in estuaries that could be considered

adverse, and that the current secondary standards do not provide adequate protection from such effects.

Having reached these conclusions, the Administrator determined that it was appropriate to consider alternative standards that are ecologically relevant. These considerations, as discussed below in section III, supported the conclusion that the current secondary standards are neither appropriate nor adequate to protect against deposition-related effects.

C. Comments on Adequacy of the Current Standards

The above sections outline the effects evidence and assessments (section II.A) used by the Administrator to inform her proposed judgments about the adequacy of the current secondary NO₂ and SO₂ standards with regard to both direct effects associated with gas-phase oxides of nitrogen and sulfur (section II.B.1) as well effects associated with deposition of oxides of nitrogen and sulfur to sensitive aquatic and terrestrial ecosystems (section II.B.2). This section discusses the comments received from the public regarding the adequacy of the current secondary standards with regard to both direct and deposition-related effects. Comments related to the EPA’s authority to address deposition-related effects through the NAAQS are discussed above in section I.E. Comments related to the EPA’s proposed conclusions regarding alternative secondary standards are discussed below in section III.D.

1. Adequacy of Current Secondary Standards To Address Direct Effects

The current secondary NO₂ and SO₂ secondary standards were set in 1971 to protect against direct effects of gaseous oxides of nitrogen and sulfur. For oxides of nitrogen, the current secondary NO₂ standard is an annual standard set to protect against adverse effects on vegetation from direct exposure to ambient oxides of nitrogen. For oxides of sulfur, the current secondary standard is a 3-hour standard intended to provide protection for plants from the direct foliar damage associated with atmospheric concentrations of SO₂. As discussed above in section II.B.1, the Administrator proposed to conclude that the current secondary standards are adequate to protect against direct phytotoxic effects on vegetation, and proposed to retain the current standards for that purpose. Many commenters supported the EPA’s proposed decision to retain the current secondary standards for various reasons related to their comments on alternative standards (as discussed below in section III.D), a

few commenters (Alliance of Automobile Manufacturers (AAM), Pennsylvania Dept. of Environmental Protection) specifically expressed the view that the current standards provide requisite protection from the direct effects on vegetation from exposures to gaseous oxides of nitrogen and sulfur, and no commenters opposed retention of the current secondary standards.

2. Adequacy of Current Secondary Standards to Address Deposition-Related Effects

As discussed above in section II.B.2, with regard to deposition-related effects, the Administrator proposed to conclude that the elements of the current secondary standards are not ecologically relevant, and thus not appropriate to provide protection of ecosystems, and that they do not provide adequate protection from such acidification and nutrient enrichment effects in both aquatic and terrestrial ecosystems. Having reached these proposed conclusions, she determined that it was appropriate to consider alternative standards that are ecologically relevant.

One group of commenters that addressed the adequacy of the current standards with regard to deposition-related effects included environmental organizations (Earthjustice, on behalf of the Appalachian Mountain Club, National Parks Conservation Association, Sierra Club, and Clean Air Council; the Center for Biological Diversity; the Nature Conservancy; Adirondack Council; Chesapeake Bay Foundation), the U.S. Department of the Interior, NESCAUM, New York Dept. of Environmental Conservation, and two tribes. These commenters generally expressed the view that the current secondary standards do not provide adequate protection from deposition-related effects. More specifically, some of these commenters stated that there was overwhelming evidence of adversity to sensitive aquatic ecosystems from acidifying deposition. These commenters cited a broad range of scientific evidence that aquatic acidification was ongoing under current conditions allowed by the current secondary standards, and that this acidification represented an adverse effect on public welfare. Several commenters noted that CASAC had agreed that deposition-related effects were ongoing and harmful and that current standards were not adequate to prevent these effects.

Among these commenters, some also expressed the view that current standards were not adequate to protect against terrestrial acidification or nutrient enrichment. The Department of

the Interior as well as Earthjustice noted that the current standards were not sufficient for these additional endpoints and cited ongoing harm under current conditions. Two tribes and the Center for Biological Diversity expressed the view that there was sufficient information to judge that the current standards were not adequate to protect against the adverse welfare effect of mercury methylation, contrary to the EPA's proposed conclusion that the available evidence was not sufficient to reach such a judgment. For example, The Forest County Potawatomi Community provided several citations regarding the relationships between aquatic acidification and mercury methylation and stated that there was sufficient evidence to find that the current standards were not adequate.

With regard to the adequacy of the current secondary standards for NO₂ and SO₂, the EPA concurs with commenters' assertions that the current standards do not provide adequate protection for ecosystems that are sensitive to aquatic acidification and that effects to these ecosystems are ongoing from ambient deposition of oxides of nitrogen and oxides of sulfur. The EPA also agrees that there is sufficient evidence to conclude that ambient deposition under the current secondary standards is causing or contributing to terrestrial acidification as well as nutrient enrichment in sensitive ecosystems. A complete discussion of considerations with regard to adequacy can be found in section II.B above. In short, the ISA has established that the major effects of concern for this review of the oxides of nitrogen and sulfur standards are associated with deposition of nitrogen and sulfur caused by atmospheric concentrations of oxides of nitrogen and sulfur. The current standards are not directed toward depositional effects, and none of the elements of the current NAAQS—indicator, form, averaging time, and level—are suited for addressing the effects of nitrogen and sulfur deposition. Additionally, although the proportion of total nitrogen loadings associated with atmospheric deposition of nitrogen varies across locations, the ISA indicates that atmospheric nitrogen deposition is the main source of new anthropogenic nitrogen to most headwater streams, high elevation lakes, and low-order streams. Atmospheric nitrogen deposition contributes to the total nitrogen load in terrestrial, wetland, freshwater and estuarine ecosystems that receive nitrogen through multiple pathways.

There are expansive data to indicate that the levels of deposition under the

current standards are not sufficient to prevent adverse effects in ecosystems. With regard to aquatic acidification, recent data indicate that in the Adirondacks and Shenandoah areas, rates of acidifying deposition of oxides of nitrogen and sulfur are still well above pre-acidification (1860) conditions. Forty-four percent of Adirondack lakes and 85 percent of Shenandoah streams evaluated exceed the critical load for an ANC of 50 µeq/L, and have suffered loss of sensitive fish species. With regard to terrestrial acidification, the REA evaluated a small number of sensitive areas as case studies and showed the potential for reduced growth. When the methodology was extended to a 27-state region, similar results were found to indicate the potential for growth effects in sensitive forests. Nitrogen deposition can alter species composition and cause eutrophication in freshwater systems. In the Rocky Mountains, for example, current deposition levels, which are within the range associated with ambient nitrogen oxide levels meeting the current standard, are known to cause changes in species composition in diatom communities indicating impaired water quality. With regard to terrestrial nutrient enrichment, most terrestrial ecosystems in the United States are nitrogen-limited, and therefore they are sensitive to perturbation caused by nitrogen additions. Under recent conditions, nearly all of the known sensitive mixed conifer forest ecosystems receive total nitrogen deposition levels above the ecological benchmark for changes in lichen species. In addition, in Coastal Sage Scrub ecosystems in California, nitrogen deposition exceeds the benchmark above which nitrogen is no longer a limiting nutrient, leading to potential alterations in ecosystem composition. Therefore, the EPA concludes that the current standards are not adequate for these effects.

The EPA, however, while agreeing that there is a causal effect between deposition of sulfur and mercury methylation disagrees that there is sufficient evidence to make the quantitative associations that would be necessary to determine that the current standards were not adequate to protect against mercury methylation. The ISA concluded that evidence is sufficient to infer a casual relationship between sulfur deposition and increased mercury methylation in wetlands and aquatic environments. Since the rate of mercury methylation varies according to several spatial and biogeochemical factors whose influence has not been fully

quantified, the correlation between sulfur deposition and methylmercury could not be quantified for the purpose of interpolating the association across waterbodies or regions. Therefore, since we are unable to quantify the relationship between atmospherically deposited oxides of sulfur and mercury methylation we cannot assess adequacy of protection. This subject is discussed more fully in section 6.2 of the REA (U.S. EPA, 2009).

Another group of commenters, (e.g. Utility Air Regulatory Group (UARG), Electric Power Research Institute (EPRI), American Petroleum Institute (API), AAM, and American Road and Transportation Builders Association (ARTBA)) generally took the position that the currently available information was not sufficient to make informed judgments about the adequacy of the current standards to address aquatic acidification effects. These commenters generally based this view on the complex nature of the interactions between pollutants and ecosystems and uncertainties in the models and analyses considered in this review. Several commenters asserted that there was not sufficient data available to determine the relationship between acidifying deposition of oxides of nitrogen and sulfur and adverse effects on aquatic ecosystems, such that there was not sufficient information to allow for the assessment of the adequacy of the current standards to provide appropriate protection from this effect. For example, AAM noted the uncertainties in models relating to dry deposition and questioned the linkages between ambient concentrations of oxides of nitrogen and sulfur and the amount of nitrogen and sulfur deposition. In addition to commenting on data limitations, UARG also expressed the view that the ecosystem services analyses included in the proposal were insufficient to make judgments about adversity to aquatic ecosystems resulting from acidifying deposition and that there is a lack of evidence demonstrating that quantifiable changes in public welfare would result from reductions in acidifying deposition. Many commenters within this group did not directly comment on the adequacy of the current standards to protect against aquatic acidification or other deposition-related effects, but instead expressed the view that the EPA did not have the authority to consider deposition-related effects in general or aquatic acidification in particular through the NAAQS. This comment and

the EPA's response are discussed above in section I.E.

With regard to the adequacy of the current standards to protect against aquatic acidification, the EPA disagrees with commenters' assertion that there is insufficient data to make linkages between deposition from the atmosphere and aquatic acidification effects. To the contrary, the EPA is confident that there is sufficient robust science to conclude that aquatic acidification is ongoing in sensitive ecosystems, that ambient deposition of oxides of nitrogen and oxides of sulfur are causative in many ecosystems nationwide and that the current standards are neither appropriate in form nor adequate in level to protect against such effects. The ISA concluded that there was a causal relationship between deposition of oxides of nitrogen and sulfur and NH_x and acidification of ecosystems. In addition, the ISA found that effects of acidifying deposition on ecosystems have been well studied over the past several decades, that vulnerable areas have been identified for the United States and that the wealth of available data has led to the development of robust ecological models used for predicting soil and surface water acidification. With regard to the scope of effects, the REA also concluded that the available data are robust and considered high quality. There is high confidence about the use of these data and their value for extrapolating to larger spatial areas. The EPA TIME/LTM network represents a source of long-term, representative sampling. Data on sulfate concentrations, nitrate concentrations and ANC from 1990 to 2006 used for this analysis as well as the EPA EMAP and Regional Environmental Monitoring and Assessment Program (REMAP) surveys, provide considerable data on surface water trends.

The EPA also disagrees with commenters' assessment of limitations in wet and dry deposition modeling. Further discussion of characterizing deposition with models can be found in section IV.C. Additionally, while the EPA recognizes that there are limitations associated with modeled deposition values, the linkages between model estimates of deposition and areas exhibiting aquatic acidification effects are consistent and persuasive in considering adequacy of the current standard. Section 2.3 of the PA and sections 2.8 and 2.10 of the ISA provide additional detailed discussions of deposition modeling and spatial resolution for deposition. CASAC concurred with the EPA's conclusion on this matter and encouraged the EPA to

move forward in developing a new form of a standard which would address aquatic acidification. Thus, while the EPA is fully mindful of the limitations and uncertainties associated with the data and models, the EPA concludes that the available evidence provides strong scientific support for the view that harm from aquatic acidification is ongoing and attributable in large part to atmospheric deposition of reactive nitrogen and sulfur.

With regard to the commenters' reliance on ecosystem services analyses included in the proposal to make judgments about adversity and public welfare, the EPA disagrees that comprehensive ecosystems services analyses are necessary to determine adversity. Ecosystem services analyses are used in this review to inform the decisions made with regard to adequacy and as such are used in conjunction with other considerations in the discussion of adversity to public welfare. Section 4 of the PA further refines this discussion of adversity to public welfare. Additionally, the paradigm of adversity to public welfare as deriving from disruptions in ecosystem structure and function has been used broadly by the EPA to categorize effects of pollutants from the cellular to the ecosystem level. An evaluation of adversity to public welfare might consider the likelihood, type, magnitude, and spatial scale of the effect as well as the potential for recovery and any uncertainties relating to these considerations. Within this context, ecosystems services analyses are one of many tools used in this review to help inform the Administrator's decision on adversity. The EPA concludes that the analyses performed as part of this review are sufficient to support the decisions made by the Administrator with regard to the adequacy of the current standards.

D. Final Decisions on the Adequacy of the Current Standards

Based on the considerations discussed above, including CASAC advice and public comments, the Administrator believes that the conclusions reached in the proposed rule with regard to the adequacy of the current secondary standards for oxides of nitrogen and sulfur for direct and deposition-related effects continue to be valid. The Administrator recognizes that the purpose of the secondary standard is to protect against "adverse" effects resulting from exposure to oxides of nitrogen and sulfur, discussed above in section II.A. The Administrator also recognizes the need for conclusions as to the adequacy of the current standards

for both direct and deposition-related effects as well as conclusions as to the appropriateness and ecological relevance of the current standards.

In considering what constitutes an ecological effect that is also adverse to the public welfare, the Administrator took into account the ISA conclusions regarding the nature and strength of the effects evidence, the risk and exposure assessment results, the degree to which the associated uncertainties should be considered in interpreting the results, the conclusions presented in the PA, and the views of CASAC and members of the public. On these bases, the Administrator concludes that the current secondary standards are adequate to protect against direct phytotoxic effects on vegetation. Thus, the Administrator has decided to retain the current secondary standards for oxides of nitrogen at 53 ppb,⁴ annual average concentration, measured in the ambient air as NO_2 , and the current secondary standard for oxides of sulfur at 0.5 ppm, 3-hour average concentration, measured in the ambient air as SO_2 .

With regard to deposition-related effects, the Administrator first considered the appropriateness of the structure of the current secondary standards to address ecological effects of concern. Based on the evidence as well as considering the advice given by CASAC and public comments on this matter, the Administrator concludes that the elements of the current standards are not ecologically relevant and thus are not appropriate to provide protection of ecosystems. On the subject of adequacy of protection with regard to deposition-related effects, the Administrator considered the full nature of ecological effects related to the deposition of ambient oxides of nitrogen and sulfur into sensitive ecosystems across the country. Her conclusions are based on the evidence presented in the ISA with regard to acidification and nutrient enrichment effects, the findings of the REA with regard to scope and severity of the current and likely future effects of deposition, the synthesis of both the scientific evidence and risk and exposure results in the PA as to the adequacy of the current standards, and the advice of CASAC and public comments. After such consideration, the Administrator concludes that current levels of oxides of nitrogen and sulfur are sufficient to cause acidification of

⁴ The annual secondary standard for oxides of nitrogen is being specified in units of ppb to conform to the current version of the annual primary standard, as specified in the final rule for the most recent review of the NO_2 primary NAAQS (75 FR 6531; February 9, 2010).

both aquatic and terrestrial ecosystems, nutrient enrichment of terrestrial ecosystems and contribute to nutrient enrichment effects in estuaries that could be considered adverse, and the current secondary standards do not provide adequate protection from such effects.

Having reached these conclusions, the Administrator determined that it was appropriate to consider alternative standards that are ecologically relevant, as discussed below in section III. These considerations further support her conclusion that the current secondary standards for oxides of nitrogen and sulfur are neither appropriate nor adequate to protect against deposition-related effects.

III. Rationale for Final Decisions on Alternative Secondary Standards

This section presents the rationale for the Administrator's final decisions regarding alternative secondary standards for oxides of nitrogen and sulfur to address deposition-related effects. Section III.A provides an overview of the aquatic acidification index (AAI) approach presented in the PA to address such effects related to aquatic acidification. Advice from CASAC on such a new approach is presented in section III.B. The Administrator's proposed conclusions on an AAI-based standard are presented in section III.C. Comments on an AAI-based standard are discussed in section III.D as well as in the Response to Comments document. The Administrator's final decisions regarding alternative secondary standards are presented in section III.E.

A. Overview of AAI Approach

Having reached the conclusion in the proposal that the current NO₂ and SO₂ secondary standards are not adequate to provide appropriate protection against potentially adverse deposition-related effects associated with oxides of nitrogen and sulfur, the Administrator then considered what new multi-pollutant standard might be appropriate, at this time, to address such effects on public welfare. The Administrator recognizes that the inherently complex and variable linkages between ambient concentrations of nitrogen and sulfur oxides, the related deposited forms of nitrogen and sulfur, and the ecological responses that are associated with public welfare effects call for consideration of a standard with an ecologically relevant design that reflects these linkages. The Administrator also recognizes that characterization of such complex and variable linkages in this review requires consideration of

information and analyses that have important limitations and uncertainties.

Despite its complexity, an ecologically relevant multi-pollutant standard to address deposition-related effects would still appropriately be defined in terms of the same basic elements that are used to define any NAAQS—indicator, form, averaging time, and level. The form would incorporate additional structural elements that reflect relevant multi-pollutant and multimedia attributes. These structural elements include the use of an ecological indicator, tied to the ecological effect we are focused on, and other elements that account for ecologically relevant factors other than ambient air concentrations. All of these elements would be needed to enable a linkage from ambient air indicators to the relevant ecological effect to define an ecologically relevant standard. As a result, such a standard would necessarily be more complex than the NAAQS that have been set historically to address effects associated with ambient concentrations of a single pollutant.

More specifically, the Administrator considered an ecologically relevant multi-pollutant standard to address effects associated with acidifying deposition-related to ambient concentrations of oxides of nitrogen and sulfur in sensitive aquatic ecosystems. This focus is consistent with the information presented in the ISA, REA, and PA, which highlighted the greater quantity and quality of the available evidence and assessments associated with aquatic acidification relative to the information and assessments available for other deposition-related effects, including terrestrial acidification and aquatic and terrestrial nutrient enrichment. Based on its review of these documents, CASAC agreed that aquatic acidification should be the focus for developing a new multi-pollutant standard in this review. In reaching conclusions about an air quality standard designed to address deposition-related aquatic acidification effects, the Administrator also recognizes that such a standard may also provide some degree of protection against other deposition-related effects.

As discussed in chapter 7 of the PA, the development of a new multi-pollutant ambient air quality standard to address deposition-related aquatic acidification effects recognizes that it is appropriate to consider a nationally applicable standard for protection against adverse effects of aquatic acidification on public welfare. At the same time, the PA recognizes the complex and heterogeneous interactions

between ambient air concentrations of nitrogen and sulfur oxides, the related deposition of nitrogen and sulfur, and associated ecological responses. The development of such a standard also needs to take into account the limitations and uncertainties in the available information and analyses upon which characterization of such interactions are based. The approach used in the PA also recognizes that while such a standard would be national in scope and coverage, the effects to public welfare from aquatic acidification will not occur to the same extent in all locations in the United States, given the inherent variability of the responses of aquatic systems to the effects of acidifying deposition. This contrasts with the relatively more homogeneous relationships between ambient air concentrations of air pollutants and the associated inhalation exposures and related public health responses that are typically considered in setting primary NAAQS.

As discussed above in section II–A, many locations in the United States are naturally protected against acid deposition due to underlying geological conditions. Likewise, some locations in the United States, including lands managed for commercial agriculture and forestry, are not likely to be negatively impacted by current levels of nitrogen and sulfur deposition. As a result, while a new ecologically relevant secondary standard would apply everywhere, it would be structured to account for differences in the sensitivity of ecosystems across the country. This would allow for appropriate protection of sensitive aquatic ecosystems, which are relatively pristine and wild and generally in rural areas, and the services provided by such sensitive ecosystems, without requiring more protection than is needed elsewhere.

As discussed below, the multi-pollutant standard developed in the PA would employ (1) Total reactive oxidized nitrogen (NO_x) and oxides of sulfur (SO_x) as the atmospheric ambient air indicators; (2) a form that takes into account variable factors, such as atmospheric and ecosystem conditions that modify the amounts of deposited nitrogen and sulfur; the distinction between oxidized and reduced forms of nitrogen; effects of deposited nitrogen and sulfur on aquatic ecosystems in terms of the ecological indicator ANC; and the representativeness of water bodies within a defined spatial area; (3) a multi-year averaging time, and (4) a standard level defined in terms of a single, national target ANC value that, in the context of the above form, identifies the various levels of

concentrations of NO_y and SO_x in the ambient air that would meet the standard. The form of such a standard has been defined by an index, AAI, which reflects the relationship between ambient concentrations of NO_y and SO_x and aquatic acidification effects that result from nitrogen and sulfur deposition-related to these ambient concentrations.

In summarizing the considerations associated with such an air quality standard to address deposition-related aquatic acidification effects, as discussed more fully in sections III.A–F of the proposal and in the PA, the following sections focus on each element of the standard, including ambient air indicators (section III.A.1), form (section III.A.2), averaging time (section III.A.3), and level (section III.A.4). Considerations related to important uncertainties inherent in such an approach are discussed in section III.A.5.

1. Ambient Air Indicators

The PA concludes that ambient air indicators other than NO₂ and SO₂ should be considered as the appropriate indicators of oxides of nitrogen and sulfur in the ambient air for protection against the acidification effects associated with deposition of the associated nitrogen and sulfur. This conclusion is based on the recognition that all forms of nitrogen and sulfur in the ambient air contribute to deposition and resulting acidification, and as such, NO₂ and SO₂ are incomplete ambient air indicators. In principle, the indicators should represent the species that are associated with oxides of nitrogen and sulfur in the ambient air and can contribute acidifying deposition. This includes both the species of oxides of nitrogen and sulfur that are directly emitted as well as species transformed in the atmosphere from oxides of nitrogen and sulfur that retain the

nitrogen and sulfur atoms from directly emitted oxides of nitrogen and sulfur. All of these compounds are associated with oxides of nitrogen and sulfur in the ambient air and can contribute to acidifying deposition.

The PA focuses in particular on the various compounds with nitrogen or sulfur atoms that are associated with oxides of nitrogen and sulfur, because the acidifying potential is specific to nitrogen and sulfur, and not other atoms (e.g., H, C, O) whether derived from the original source of oxides of nitrogen and sulfur emissions or from atmospheric transformations. For example, the acidifying potential of each molecule of NO₂, NO, HNO₃ or PAN is identical, as is the potential for each molecule of SO₂ or ion of particulate sulfate (p-SO₄). Each atom of sulfur affords twice the acidifying potential of each atom of nitrogen.

a. Oxides of Sulfur

As discussed in the PA (U.S. EPA, 2011, section 7.1.1), oxides of sulfur include the gases sulfur monoxide (SO), SO₂, sulfur trioxide (SO₃), disulfur monoxide (S₂O), and particulate-phase sulfur compounds (referred to as SO₄) that result from gas-phase sulfur oxides interacting with particles. However, the sum of SO₂ and SO₄ does represent virtually the entire ambient air mass of sulfur that contributes to acidification. In addition to accounting for virtually all the potential for acidification from oxidized sulfur in the ambient air, there are reliable methods to monitor the concentrations of SO₂ and particulate SO₄. The PA concludes that the sum of SO₂ and SO₄, referred to as SO_x, are appropriate ambient air indicators of oxides of sulfur because they represent virtually all of the acidification potential of ambient air oxides of sulfur and there are reliable methods suitable for measuring SO₂ and SO₄.

b. Oxides of Nitrogen

As discussed in the PA (U.S. EPA, 2011, section 7.1.2), NO_y, as defined in chapter 2 of the PA, incorporates basically all of the oxidized nitrogen species that have acidifying potential and as such, NO_y should be considered as an appropriate indicator for oxides of nitrogen. Total reactive oxidized nitrogen is an aggregate measure of NO and NO₂ and all of the reactive oxidized products of NO and NO₂. That is, NO_y is a group of nitrogen compounds in which all of the compounds are either an oxide of nitrogen or compounds in which the nitrogen atoms come from oxides of nitrogen. Total reactive oxidized nitrogen is especially relevant as an ambient indicator for acidification in that it both relates to the oxides of nitrogen in the ambient air and also represents the acidification potential of all oxidized nitrogen species in the ambient air, whether an oxide of nitrogen or derived from oxides of nitrogen. The merits of other individual NO_y species, particularly total nitrate, are discussed in section 2 of the PA.

2. Form

Based on the evidence of the aquatic acidification effects caused by the deposition of NO_y and SO_x, the PA (U.S. EPA, 2011, section 7.2) presents the development of a new form that is ecologically relevant for addressing such effects. The conceptual design for the form of such a standard includes three main components: an ecological indicator, deposition metrics that relate to the ecological indicator, and a function that relates ambient air indicators to deposition metrics. Collectively, these three components link the ecological indicator to ambient air indicators, as illustrated below in Fig III–1.

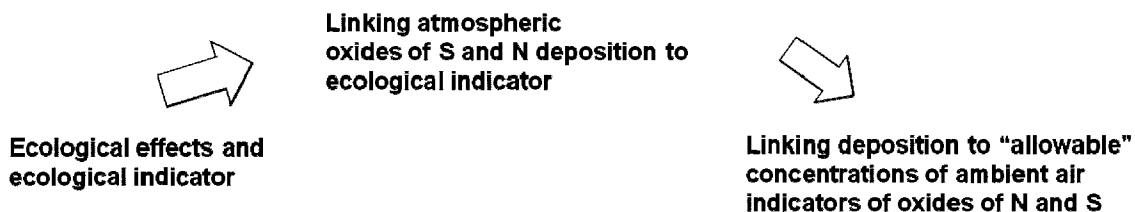


Figure III-1. Conceptual design of the form of an aquatic acidification standard for oxides of nitrogen and sulfur

The simplified flow diagram in Figure III–1 compresses the various atmospheric, biological, and geochemical processes associated with acidifying deposition to aquatic ecosystems into a simplified conceptual picture. The ecological indicator (left box) is related to atmospheric deposition through biogeochemical ecosystem models (middle box), which associate a target deposition load to a target ecological indicator. Once a target deposition is established, associated allowable air concentrations are determined (right box) through the relationships between ambient air concentration and deposition that are embodied in air quality models such as CMAQ. The PA describes the development and rationale for each of these components, as well the integration of these components into the full expression of the form of the standard using the concept of a national AAI that represents a target ANC level as a function of ambient air concentrations.

The AAI was designed to be an ecologically relevant form of the standard that determines the levels of NO_y and SO_x in the ambient air that would achieve a target ANC limit for the United States. The intent of the AAI is to weight atmospheric concentrations of oxides of nitrogen and sulfur by their propensity to contribute to acidification through deposition, given the fundamental acidifying potential of each pollutant, and to take into account the ecological factors that govern acid sensitivity in different ecosystems. The index also accounts for the contribution of reduced nitrogen to acidification. Thus, the AAI encompasses those attributes of specific relevance to protecting ecosystems from the acidifying potential of ambient air concentrations of NO_y and SO_x.

a. Ecological Indicator

This section summarizes the rationale in the PA for selecting ANC as the appropriate ecological indicator for consideration. Recognizing that ANC is not itself the causative or toxic agent for adverse aquatic acidification effects, the rationale for using ANC as the relevant ecological indicator is based on the following:

(1) The ANC is directly associated with the causative agents, pH and dissolved Al, both through empirical evidence and mechanistic relationships;

(2) Empirical evidence shows very clear and strong relationships between adverse effects and ANC;

(3) The ANC is a more reliable indicator from a modeling perspective, allowing use of a body of studies and technical analyses related to ANC and acidification to inform the development of the standard; and

(4) The ANC embodies the concept of acidification as posed by the basic principles of acid base chemistry and the measurement method used to estimate ANC and, therefore, serves as a direct index to protect against acidification.

Because ANC clearly links both to biological effects of aquatic acidification as well as to acidifying inputs of NO_y and SO_x deposition, the PA concludes that ANC is an appropriate ecological indicator for relating adverse aquatic ecosystem effects to acidifying atmospheric deposition of SO_x and NO_y, and is preferred to other potential indicators. In reaching this conclusion, the PA notes that in its review of the first draft PA, CASAC concluded that “information on levels of ANC protective to fish and other aquatic biota has been well developed and presents probably the lowest level of uncertainty in the entire methodology” (Russell and Samet, 2010a). In its more recent review of the second draft PA, CASAC agreed “that acid neutralizing capacity is an appropriate ecological measure for reflecting the effects of aquatic acidification” (Russell and Samet, 2010b; p. 4).

b. Linking ANC to Deposition

There is evidence to support a quantified relationship between deposition of nitrogen and sulfur and ANC. This relationship was analyzed in the REA for two case study areas, the Adirondack and Shenandoah Mountains, based on time-series modeling and observed trends. In the REA analysis, long-term trends in surface water nitrate, sulfate and ANC were modeled using MAGIC for the two case study areas. These data were used to compare recent surface water conditions in 2006 with preindustrial conditions (i.e., preacidification 1860). The results showed a marked increase in the number of lakes affected by acidifying deposition, characterized as a decrease in ANC levels, since the onset of anthropogenic nitrogen and sulfur deposition, as discussed in chapter 2 of the PA.

In the REA, the quantified relationship between deposition and ANC was investigated using ecosystem acidification models, also referred to as acid balance models or critical loads models (U.S. EPA, 2011, section 2 and U.S. EPA, 2009, section 4 and Appendix 4). These models quantify the relationship between deposition of nitrogen and sulfur and the resulting ANC in surface waters based on an ecosystem’s inherent generation of ANC and ability to neutralize nitrogen deposition through biological and physical processes. A critical load is defined as the amount of acidifying atmospheric deposition of nitrogen and sulfur beyond which a target ANC is not reached. Relatively high critical load values imply that an ecosystem can accommodate greater deposition levels than lower critical loads for a specific target ANC level. Ecosystem models that calculate critical loads form the basis for linking deposition to ANC.

As discussed in chapter 2 of the PA, both dynamic and steady-state models calculate ANC as a function of ecosystem attributes and atmospheric nitrogen and sulfur deposition, and can be used to calculate critical loads. Steady-state models are time invariant and reflect the long-term consequences associated with an ecosystem reaching equilibrium under a constant level of atmospheric deposition. Dynamic models are time variant and take into account the time dependencies inherent in ecosystem hydrology, soil and biological processes. Dynamic models like MAGIC can provide the time-series response of ANC to deposition whereas steady-state models provide a single ANC relationship to any fixed deposition level. Dynamic models naturally are more complex than steady-state models as they attempt to capture as much of the fundamental biogeochemical processes as practicable, whereas steady-state models depend on far greater parameterization and generalization of processes that is afforded, to some degree, by not having to account for temporal variability.

In the PA, a steady-state model is used to define the relevant critical load, which is the amount of atmospheric deposition of nitrogen (N) and sulfur (S) beyond which a target ANC is not achieved and sustained.⁵ It is expressed as:

⁵ This section discusses the linkages between deposition of nitrogen and sulfur and ANC. Section

III.A.2.c then discusses the linkages between

atmospheric concentrations of NO_y and SO_x and deposition of nitrogen and sulfur.

$$CL_{ANCLim}(N + S) = ([BC]_0^* - [ANC_{lim}])Q + Neco \quad (III-1)$$

Where:

$CL_{ANCLim}(N + S)$ is the critical load of deposition, with units of equivalent charge/(area-time);
 $[BC]_0^*$ is the natural contribution of base cations from weathering, soil processes and preindustrial deposition, with units of equivalent charge/volume;
 $[ANC_{lim}]$ is the target ANC value, with units of equivalent charge/volume;
 Q is the catchment level runoff rate governed by water mass balance and dominated by precipitation, with units of distance/time; and
 $Neco$ is the amount of nitrogen deposition that is effectively neutralized by a variety of biological (e.g., nutrient uptake) and physical processes, with units of equivalent charge/(area-time).

Equation III-1 is a modified expression that adopts the basic formulation of the steady-state models that are described in chapter 2 of the PA. More detailed discussion of the rationale, assumptions and derivation of equation III-1, as well as all of the equations in this section, are included in Appendix B of the PA. The equation simply reflects the amount of deposition of nitrogen and sulfur from the atmosphere, $CL_{ANCLim}(N + S)$, that is associated with a sustainable long-term ANC target, $[ANC_{lim}]$, given the capacity of the natural system to generate ANC, $[BC]_0^*$, and the capacity of the natural system to neutralize nitrogen deposition, $Neco$. This expression of critical load is valid when nitrogen

deposition is greater than $Neco$.⁶ The runoff rate, Q , allows for balancing mass in the two environmental mediums— atmosphere and catchment. This critical load expression can be focused on a single water system or more broadly. To extend applicability of the critical load expression (equation III-1) from the catchment level to broader spatial areas, the terms Q_r and CL_r are used, which are the runoff rate and critical load, respectively, of the region over which all the atmospheric terms in the equation are defined.

As presented above, the terms S and N in the $CL_{ANCLim}(N + S)$ term broadly represent all species of sulfur or nitrogen that can contribute to acidifying deposition. This follows conventions used in the scientific literature that addresses critical loads, and it reflects all possible acidifying contributions from any sulfur or nitrogen species. For all practical purposes, S reflects SO_x as described above, the sum of sulfur dioxide gas and particulate sulfate. However, N in equation III-1 includes both oxidized forms, consistent with the ambient indicator, NO_y , in addition to the reduced nitrogen species, ammonia and ammonium ion, referred to as NH_x . The NH_x is included in the critical load formulation because it contributes to potentially acidifying nitrogen deposition. Consequently, from a mass balance or modeling perspective, the

form of the standard needs to account for NH_x , as described below.

c. Linking Deposition to Ambient Air Indicators

The last major component of the form illustrated in Figure III-1 addresses the linkage between deposition of nitrogen and sulfur and concentrations of the ambient air indicators, NO_y and SO_x . To link ambient air concentrations with deposition, the PA defines a transference ratio, T , as the ratio of total wet and dry deposition to ambient concentration, consistent with the area and time period over which the standard is defined. To express deposition of NO_y and SO_x in terms of NO_y and SO_x ambient concentrations, two transference ratios were defined, where T_{SO_x} equals the ratio of the combined dry and wet deposition of SO_x to the ambient air concentration of SO_x , and T_{NO_y} equals the ratio of the combined dry and wet deposition of NO_y to the ambient air concentration of NO_y .

As described in chapter 7 of the PA, reduced forms of nitrogen (NH_x) are included in total nitrogen in the critical load equation, III-1. Reduced forms of nitrogen are treated separately, as are NO_y and SO_x , and the transference ratios are applied. This results in the following critical load expression that is defined explicitly in terms of the indicators NO_y and SO_x :

$$CL_{ANCLim}(N + S) = ([BC]_0^* - [ANC_{lim}])Q + Neco = [NO_y]T_{NO_y} + [SO_x]T_{SO_x} + NH_x \quad (III-2)$$

This is the same equation as III-1, with the deposition associated with the critical load translated to deposition from ambient air concentrations via transference ratios. In addition, deposition of reduced nitrogen, oxidized nitrogen and oxidized sulfur are treated separately.

Transference ratios are a modeled construct, and therefore cannot be compared directly to measurable

quantities. Section III.B.3 of the proposal discusses approaches to quantifying these ratios that consider blending observational data and models. The PA more fully discusses the rationale underlying transference ratios, as well as analyses illustrating the relative stability and variability of these ratios.

d. Aquatic Acidification Index

Having established the transference ratios that translate atmospheric concentrations to deposition of nitrogen and sulfur and the various expressions that link atmospheric deposition of nitrogen and sulfur to ANC, the PA derived the following expression of these linkages, which separates reduced forms of nitrogen, NH_x , from oxidized forms:

$$ANC_{calc} = \{ANCLim + CL_r/Q_r\} - NH_x/Q_r - T_{NO_y}[NO_y]/Q_r - T_{SO_x}[SO_x]/Q_r \quad (III-3)$$

⁶ Because $Neco$ is only relevant to nitrogen deposition, in rare cases where $Neco$ is greater than

the total nitrogen deposition, the critical load would be defined only in terms of acidifying

deposition of sulfur and the $Neco$ term in equation III-1 would be set to zero.

Equation III-3 is the basic expression of the form of a standard that translates the conceptual framework into an explicit expression that defines ANC as a function of the ambient air indicators, NO_y and SO_x, reduced nitrogen deposition,⁷ and the critical load

necessary to achieve a target ANC level. This equation calculates an expected ANC value based on ambient concentrations of NO_y and SO_x. The calculated ANC will differ from the target ANC (ANCLim) depending on how much the nitrogen and sulfur deposition

associated with NO_y, SO_x, and NH_x differs from the critical load associated with just achieving the target ANC.

Based on equation III-3, the PA defines an AAI that is more simply stated using terms that highlight the ambient air indicators:

$$AAI = F1 - F2 - F3[NO_y] - F4[SO_x] \quad (III-4)$$

where the AAI represents the long-term (or steady-state) ANC level associated with ambient air concentrations of NO_y and SO_x. The factors F1 through F4 convey three attributes: a relative measure of the ecosystem's ability to neutralize acids (F1), the acidifying potential of reduced nitrogen deposition (F2), and the deposition-to-concentration translators for NO_y (F3) and SO_x (F4).

Specifically:

F1 = ANCLim + CL_r/Q_r;

F2 = NH_x/Q_r = NH_x deposition divided by Q_r;

F3 = T_{NO_y}/Q_r; T_{NO_y} is the transference ratio that converts ambient air concentrations of NO_y to deposition of NO_y; and

F4 = T_{SO_x}/Q_r; T_{SO_x} is the transference ratio that converts ambient air concentrations of SO_x to deposition of SO_x.

All of these factors include representative Q_r to maintain unit (and mass) consistency between the AAI and the terms on the right side of equation III-4.

The F1 factor is the target ANC level plus the amount of deposition (critical load) the ecosystem can receive and still achieve the target level. It incorporates an ecosystem's ability to generate acid neutralizing capacity through base cation supply ([BC]*a) and to neutralize acidifying nitrogen deposition through *Neco*, both of which are incorporated in the CL term. As noted above, because *Neco* can only neutralize nitrogen deposition (oxidized or reduced) there may be rare cases where *Neco* exceeds the combination of reduced and oxidized nitrogen deposition. Consequently, to ensure that the AAI equation is applicable in all cases that may occur, equation III-4 is conditional on total nitrogen deposition, {NH_x + F3[NO_y]}, being greater than *Neco*. In rare cases where *Neco* is greater than {NH_x + F3[NO_y]}, F2, F3, and *Neco* would be set equal to 0 in the AAI equation. The consequence of setting F2 and F3 to zero is simply to constrain the AAI calculation just to SO_x, as nitrogen would have no bearing on acidifying contributions in this case.

The PA concludes that equation III-4 (U.S. EPA, 2011, equation 7-12), which

defines the AAI, is ecologically relevant and appropriate for use as the form of a national standard designed to provide protection for aquatic ecosystems from the effects of acidifying deposition associated with concentrations of oxides of nitrogen and sulfur in the ambient air. This AAI equation does not, however, in itself, define the spatial areas over which the terms of the equation would apply. To specify values for factors F1 through F4, it is necessary to define spatial areas over which these factors are determined. Thus, it is necessary to identify an approach for spatially aggregating water bodies into ecologically meaningful regions across the United States, as discussed below.

e. Spatial Aggregation

As discussed in the PA, one of the unique aspects of this form is the need to consider the spatial areas over which values for the F factors in the AAI equation are quantified. Ecosystems across the United States exhibit a wide range of geological, hydrological and vegetation characteristics that influence greatly the ecosystem parameters, Q, BC_o* and *Neco* that are incorporated in the AAI. Variations in ecosystem attributes naturally lead to wide variability in the sensitivities of water bodies in the United States to acidification, as well as in the responsiveness of water bodies to changes in acidifying deposition. Consequently, variations in ecosystem sensitivity, and the uncertainties inherent in characterizing these variations, must be taken into account in developing a national standard. In developing a secondary NAAQS to protect public welfare, the focus of the PA is on protecting sensitive populations of water bodies, not on each individual water body, which is consistent with the Agency's approach to protecting public health through primary NAAQS that focus on susceptible populations, not on each individual.

The approach used for defining ecologically relevant regions across the United States, along with approaches to characterizing each region as acid sensitive or relatively non-acid sensitive is discussed in detail in the PA (U.S. EPA, 2011, section 7.2.5). This characterization facilitates a more detailed analysis and focus on those regions that are relatively more acid sensitive, as well as avoiding over-protection in relatively non-acid sensitive regions that would receive limited benefit from reductions in the deposition of oxides of nitrogen and sulfur with respect to aquatic acidification effects.

Based on considering available classification schemes for spatial aggregation, the PA concludes that Omernik's ecoregion classification (as described at <http://www.epa.gov/wed/pages/ecoregions>) is the most appropriate method to consider for the purposes of this review. The PA concludes that ecoregion level III (Figure IV-1) resolution, with 84 defined ecoregions in the contiguous United States,⁸ is the most appropriate level to consider for this purpose. The PA notes that the use of ecoregions is an appropriate spatial aggregation scheme for an AAI-based standard focused on deposition-related aquatic acidification effects, while many of the same ecoregion attributes may be applicable in subsequent NAAQS reviews that may address other deposition-related aquatic and terrestrial ecological effects. Because atmospheric deposition is modified by ecosystem attributes, the types of vegetation, soils, bedrock geology, and topographic features that are the basis of this ecoregion classification approach also will likely be key attributes for other deposition-related effects (e.g., terrestrial acidification, nutrient enrichment) that link atmospheric concentrations to an aquatic or terrestrial ecological indicator.

The PA used Omernik's original alkalinity data (U.S. EPA, 2011, section

⁷ Because NH_x is characterized directly as deposition, not as an ambient concentration in this

equation, no transference ratio is needed for this term.

⁸ We note that an 85th area within Omernik's Ecoregion Level III is currently being developed for California.

2) and more recent ANC data to delineate two broad groupings of ecoregions: acid-sensitive and relatively non-acid sensitive ecoregions. This delineation was made to facilitate greater focus on those ecoregions with water bodies that generally have greater acid sensitivity and to avoid over-protection in regions with generally less sensitive water bodies. The approach used to delineate acid-sensitive and relatively non-acid sensitive regions included an initial numerical-based sorting scheme using ANC data, which categorized ecoregions with relatively high ANC values as being relatively non-acid sensitive. This initial delineation resulted in 29 of the 84 Omernik ecoregions being categorized as acid sensitive. Subsequently, land use data based on the 2006 National Land Cover Data base (NLCD, <http://www.epa.gov/mrlc/nlcd-2006.html>) were also considered to determine to what extent an ecoregion is of a relatively pristine and rural nature by quantifying the degree to which active management practices related to development and agriculture occur in each ecoregion, resulting in 22 relatively acid-sensitive ecoregions (Table III–1).

TABLE III–1—LIST OF 22 ACID-SENSITIVE AREAS

Ecoregion name	Ecoregion number
Ridge and Valley	8.4.1
Northern Appalachian Plateau and Uplands	8.1.3
Piedmont	8.3.4
Western Allegheny Plateau	8.4.3
Southwestern Appalachians	8.4.9
Boston Mountains	8.4.6
Blue Ridge	8.4.4
Ouachita Mountains	8.4.8
Central Appalachians	8.4.2
Northern Lakes and Forests	5.2.1
Maine/New Brunswick Plains and Hills	8.1.8
North Central Appalachians	5.3.3
Northern Appalachian and Atlantic Maritime Highlands	5.3.1
Columbia Mountains/Northern Rockies	6.2.3
Middle Rockies	6.2.10
Wasatch and Uinta Mountains ...	6.2.13
North Cascades	6.2.5
Cascades	6.2.7
Southern Rockies	6.2.14
Sierra Nevada	6.2.12
Idaho Batholith	6.2.15
Canadian Rockies	6.2.4

Consideration was also given to the use of naturally acidic conditions in defining relatively non-acid sensitive areas. For example, several of the ecoregions located in plains near the coast exhibit elevated dissolved organic carbon (DOC) levels, which is associated

with naturally acidic conditions. The DOC in surface waters is derived from a variety of weak organic acid compounds generated from the natural availability and decomposition of organic matter from biota. Consequently, high DOC is associated with “natural” acidity, with the implication that a standard intended to protect against atmospheric contributions to acidity is not an area of focus. The evidence suggests that several of the more highly managed ecoregions in coastal or near coastal transition zones are associated with relatively high DOC values, typically exceeding on average 5 milligrams per liter, compared to other acid sensitive areas. Although there is sound logic to interpret naturally acidic areas as relatively non-acid sensitive, natural acidity indicators were not explicitly included in defining relatively non-acid sensitive areas as there does not exist a generally accepted quantifiable scientific definition of natural acidity. Approaches to explicitly define natural acidity likely will be pursued in future reviews of the standard.

Having concluded that the Omernik level III ecoregions are an appropriate approach to spatial aggregation for the purpose of a standard to address deposition-related aquatic acidification effects, the PA uses those ecoregions to define each of the factors in the AAI equation. As discussed below, factors F1 through F4 in equation III–4 are defined for each ecoregion by specifying ecoregion-specific values for each factor based on measured and modeled data.

i. Factor F1

As discussed above, factor F1 reflects a relative measure of an ecosystem’s ability to neutralize acidifying deposition, and is defined as: $F1 = \text{ANClim} + \text{CL}_r / Q_r$. The value of F1 for each ecoregion would be based on a calculated critical load used to represent the ecoregion (CL_r) associated with a single national target ANC level (ANClim , discussed below in section III.D), as well as on a runoff rate (Q_r) to represent the region. To specify ecoregion-specific values for the term Q_r , the PA used the median value of the distribution of Q values that are available for water bodies within each ecoregion. To specify ecoregion-specific values for the term CL_r in factor F1, a distribution⁹ of calculated critical loads

was created for the water bodies in each ecoregion for which sufficient water quality and hydrology data are available.¹⁰ The specified critical load was then defined to be a specific percentile of the distribution of critical loads in the ecoregion. Thus, for example, using the 90th percentile means that within an ecoregion, the goal would be for 90 percent of the water bodies to have higher calculated critical loads than the specified critical load. That is, if the specified critical load were to occur across the ecoregion, the goal would be for 90 percent of the water bodies to achieve the national ANC target or better.

The specific percentile selected as part of the definition of F1 is an important parameter that directly impacts the critical load specified to represent each ecoregion, and therefore the degree of protectiveness of the standard. A higher percentile corresponds to a lower critical load and, therefore, to lower allowable ambient air concentrations of NO_y and SO_x and related deposition to achieve a target AAI level. In conjunction with the other terms in the AAI equation, alternative forms can be appropriately characterized in part by identifying a range of alternative percentiles. The choice of an appropriate range of percentiles to consider for acid-sensitive and relatively non-acid sensitive ecoregions, respectively, is discussed below.

For relatively acid-sensitive ecoregions, the PA concludes it is appropriate to consider percentiles in the range of the 70th to the 90th percentile (of sensitivity). This conclusion is based on the judgment that it would not be appropriate to represent an ecoregion with the lowest or near lowest critical load, so as to avoid potential extreme outliers that can be seen to exist at the extreme end of the data distributions, which would not be representative of the population of acid sensitive water bodies within the ecoregion and could lead to an overly protective standard. At the same time, in considering ecoregions that are inherently acid sensitive, it is judged to be appropriate to limit the lower end of the range for consideration to the 70th percentile, a value well above the median of the distribution, so that a substantial majority of acid-sensitive water bodies are protected. Since the percentile value influences the relative

⁹ The distribution of critical loads was based on CL values calculated with Neco at the lake level. Consideration could also be given to using a distribution of CLs without Neco and adding the ecoregion average Neco value to the nth percentile critical load. This would avoid cases where the lake-level Neco value potentially could be greater

than total nitrogen deposition. The CL at the lake level represents the CL for the lake to achieve the specified national target ANC value.

¹⁰ The PA judged the data to be sufficient for this purpose if data are available from more than 10 water bodies in an ecoregion.

degree of protectiveness afforded by the AAI approach, the degree of confidence in characterizing the representativeness of sampled water bodies relative to all water bodies within an ecoregion is a critical issue, and it is important to continually improve this confidence.

For relatively non-acid sensitive ecoregions, the PA concludes it is appropriate to consider the use of a range of percentiles that extends lower than the range identified above for acid-sensitive ecoregions. Consideration of a lower percentile would avoid representing a relatively non-acid sensitive ecoregion by a critical load associated with relatively more acid-sensitive water bodies. In particular, the PA concludes it is appropriate to focus on the median or 50th percentile of the distribution of critical loads so as to avoid over-protection in such ecoregions.

ii. Factor F2, F3 and F4

As discussed above, factor F2 is the amount of reduced nitrogen deposition within an ecoregion, including the deposition of both ammonia gas and ammonium ion, and is defined as: $F2 = NH_x/Q_r$. The PA calculated the representative runoff rate, Q_r , using a similar approach as noted above for factor F1; i.e., the median value of the distribution of Q values that are available for water bodies within each ecoregion. In the PA, 2005 CMAQ model simulations over 12-km grids are used to calculate an average value of NH_x for each ecoregion. The NH_x term is based on annual average model outputs for each grid cell, which are spatially averaged across all the grid cells contained in each ecoregion to calculate a representative annual average value for each ecoregion. The PA concludes that this approach of using spatially averaged values is appropriate for modeling, largely due to the relatively rapid mixing of air masses that typically results in relatively homogeneous air quality patterns for regionally dispersed pollutants. In addition, there is greater confidence in using spatially averaged modeled atmospheric fields than in using modeled point-specific fields.

This averaging approach is also used for the air concentration and deposition terms in factors F3 and F4, which are the ratios that relate ambient air concentrations of NO_y and SO_x to the associated deposition, and are defined as follows: $F3 = T_{NO_y}/Q_r$ and $F4 = T_{SO_x}/Q_r$. T_{NO_y} is the transference ratio that converts ambient air concentrations of NO_y to deposition of NO_y and T_{SO_x} is the transference ratio that converts ambient air concentrations of SO_x to

deposition of SO_x . The transference ratios are based on the 2005 CMAQ simulations, using average values for each ecoregion, as noted above for factor F2. More specifically, the transference ratios are calculated as the annual deposition of NO_y or SO_x spatially averaged across the ecoregion and divided by the annual ambient air concentration of NO_y or SO_x , respectively, spatially averaged across the ecoregion.

f. Summary of the AAI Form

The PA developed an ecologically relevant form of an ambient air quality standard to address deposition-related aquatic acidification effects using an equation to calculate an AAI value in terms of the ambient air indicators of oxides of nitrogen and sulfur and the relevant ecological and atmospheric factors that modify the relationships between the ambient air indicators and ANC. Recognizing the spatial variability of such factors across the United States, the PA concludes it is appropriate to divide the country into ecologically relevant regions, characterized as acid-sensitive or relatively non-acid sensitive, and specify the value of each of the factors in the AAI equation for each such region.

Using the equation, a value of AAI can be calculated for any measured values of ambient NO_y and SO_x . For such a NAAQS, the Administrator would set a single, national value for the level of the AAI used to determine achievement of the NAAQS, as summarized below in section III.A.4. The ecoregion-specific values for factors F1 through F4 would be specified by the EPA based on the most recent data and CMAQ model simulations, and codified as part of such a standard. These factors would be reviewed and updated as appropriate in the context of each periodic review of the NAAQS.

3. Averaging Time

Reflecting a focus on long-term effects of acidifying deposition, the PA developed the AAI that links ambient air indicators to deposition-related ecological effects, in terms of several factors, F1 through F4. As discussed above, these factors are all calculated as annual average values, whether based on water quality and hydrology data or on CMAQ model simulations. In the context of a standard defined in terms of the AAI, the PA concludes that it is appropriate to consider the same annual averaging time for the ambient air indicators as is used for the factors in the AAI equation. As noted in chapter 3 of the ISA, protection against episodic

acidity events can be achieved by establishing a higher chronic ANC level.

The PA also considered interannual variability in both ambient air quality and in precipitation, which is directly related to the deposition of oxides of nitrogen and sulfur from the ambient air. While ambient air concentrations show year-to-year variability, often the year-to-year variability in precipitation is considerably greater, given the highly stochastic nature of precipitation. The use of multiple years over which annual averages are determined would dampen the effects of interannual variability in both air quality and precipitation. Consequently, the PA concludes that an annual averaging time based on the average of each year over a consecutive 3- to 5-year period is appropriate to consider for the ambient air indicators NO_y and SO_x .

4. Level

The PA concludes that the level of a standard for aquatic acidification based on the AAI would be defined in terms of a single, national value of the AAI. Such a standard would be met at a monitoring site when the multi-year average of the calculated annual values of the AAI was equal to or above the specified level of the standard.¹¹ The annual values of the AAI would be calculated based on the AAI equation using the assigned ecoregion-specific values for factors F1 through F4 and monitored annual average NO_y and SO_x concentrations. Since the AAI equation is based on chronic ANC as the ecological indicator, the level chosen for the standard would reflect a target chronic ANC value. The combination of the form of the standard, discussed above in section III.A.2, defined by the AAI equation and the assigned values of the F factors in the equation, other elements of the standard including the ambient air indicators (section III.A.1) and their averaging time (section III.A.3), and the level of the standard determines the allowable levels of NO_y and SO_x in the ambient air within each ecoregion. All of the elements of the standard together determine the degree of protection from adverse aquatic acidification effects associated with oxides of nitrogen and sulfur in the ambient air. The level of the standard plays a central role in determining the degree of protection provided and is discussed below.

Based on associations between pH levels and target ANC levels and

¹¹ Unlike other NAAQS, where the standard is met when the relevant value is at or below the level of the standard since a lower standard level is more protective, in this case a higher standard level is more protective.

between ANC levels and aquatic ecosystem effects, as well as consideration of episodic acidity, ecosystem response time, precedent uses of target ANC levels, and public welfare benefits, the PA concludes that consideration should be given to a range of standard AAI levels from 20 to 75 $\mu\text{eq/L}$. The available evidence indicates that target ANC levels below 20 $\mu\text{eq/L}$ would be inadequate to protect against substantial ecological effects and potential catastrophic loss of ecosystem function in some sensitive aquatic ecosystems. While ecological effects occur at ANC levels below 50 $\mu\text{eq/L}$ in some sensitive ecosystems, the degree and nature of those effects are less significant than at levels below 20 $\mu\text{eq/L}$. Levels at and above 50 $\mu\text{eq/L}$ would be expected to provide additional protection, although uncertainties regarding the potential for additional protection from adverse ecological effects are much larger for target ANC levels above about 75 $\mu\text{eq/L}$, as effects are generally appreciably less sensitive to changes in ANC at such higher levels.

The PA recognizes that the level of the standard together with the other elements of the standard, including the ambient air indicators, averaging time, and form, determine the overall protectiveness of the standard. Thus, consideration of a standard level should reflect the strengths and limitations of the evidence and assessments as well as the inherent uncertainties in the development of each of the elements of the standard. The implications of considering alternative standards, defined in terms of alternative combinations of levels and percentile values that are a critical component of factor F1 in the form of the standard, are discussed in section III.E of the proposal and more fully in the PA.

5. Characterization of Uncertainties

The characterization of uncertainties is intended to address the relative confidence associated with the linked atmospheric-ecological effects system described above, and is described in detail in the PA (U.S. EPA, 2011, section 7.6 and Appendices F and G) and summarized in section III.F of the proposal. A brief overview of uncertainties is presented here in the context of the major structural components underlying the standard, as well as with regard to areas of relatively high uncertainty.

As discussed in the PA (U.S. EPA, 2011, Table 7–3), there is relatively low uncertainty with regard to the conceptual formulation of the overall structure of the AAI-based standard that incorporates the major associations

linking biological effects to air concentrations. Based on the strength of the evidence that links species richness and mortality to water quality, the associations are strongly causal and without any obvious confounding influence. The strong association between the ecosystem indicator (ANC) and the causative water chemistry species (dissolved aluminum and hydrogen ion) reinforces the confidence in the linkage between deposition of nitrogen and sulfur and effects. This strong association between ANC and effects is supported by a sound mechanistic foundation between deposition and ANC. The same mechanistic strength holds true for the relationship between ambient air levels of nitrogen and sulfur and deposition, which completes the linkage from ambient air indicators through deposition to ecological effects.

There are much higher uncertainties, however, in considering and quantifying the specific elements within the structure of an AAI-based standard, including the deposition of SO_x , NO_y , and NH_x as well as the critical load-related component, each of which can vary within and across ecoregions. Overall system uncertainty with an AAI approach relates not just to the uncertainty in each element, but also to the combined uncertainties that result from linking these elements together within the AAI-based structure and over the defined spatial scale (i.e., ecoregions). Some of these elements—including, for example, dry deposition, pre-industrial base cation production, and reduced nitrogen deposition—are estimated with less confidence than other elements (U.S. EPA, 2011, Table 7.3). The uncertainties associated with all of these elements, and the combination of these elements through the AAI equation and over the ecoregion spatial scale, are summarized below.

The lack of observed dry deposition data, which affects confidence in the AAI on an ecoregion scale, is constrained in part by the lack of efficient measurement technologies. Progress in reducing uncertainties in dry deposition will depend on improved atmospheric concentration data and direct deposition flux measurements of the relevant suite of NO_y and SO_x species.

Pre-industrial base cation productivity by definition is not observable. Contemporary observations and inter-model comparisons are useful tools that help reduce the uncertainty in estimates of pre-industrial base cation productivity used in the AAI equation. In characterizing contemporary base cation flux using basic water quality

measurements (i.e., major anion and cation species as defined in equation 2.11 in the PA), it is reasonable to assume that a major component of contemporary base cation flux is associated with pre-industrial weathering rates. To the extent that multiple models converge on similar solutions within and across ecoregions, greater confidence in estimating pre-industrial base cation production within the AAI and ecoregion frameworks would be achieved.

While characterization of NH_x deposition has been evolving over the last decade, the high uncertainty in characterizing NH_x deposition is due to both the lack of field measurements and the inherent complexity of characterizing NH_x with respect to source emissions and dry deposition.¹² Because ammonia emissions are generated through a combination of man-made and biological activities, and ammonia is semi-volatile, the ability to characterize spatial and temporal distributions of NH_x concentrations and deposition patterns is limited. While direct measurement of NH_x deposition is resource intensive because of the diffuse nature of sources (i.e., area-wide and non-point sources), there have been more frequent deposition flux studies, relative to other nitrogen species, that enable the estimation of both emissions and dry deposition. Also, while ammonia has a relatively high deposition velocity and traditionally was thought to deposit close to the emissions release areas, the semi-volatile nature of ammonia results in re-entrainment back into the lower boundary layer of the atmosphere resulting in a more dispersed concentration pattern exhibiting transport characteristics similar to longer lived atmospheric species. These inherent complexities in source characterization and ambient concentration patterns significantly increase the degree of uncertainty in NH_x deposition in general, and in the AAI equation applied on an ecoregion scale in particular. However, the PA notes that progress is being made in measuring ammonia with cost efficient samplers and anticipates the gradual evolution of a spatially robust ammonia sampling network that would help support analyses to reduce underlying uncertainties in NH_x deposition.

In characterizing uncertainties with respect to available measurement data and the use of ecological and

¹² Field measurements of NH_x have been extremely limited, but have begun to be enhanced through the NADP's passive ammonia network (AMoN).

atmospheric models, as summarized in sections III.F.2–3 of the proposal, the PA identified data gaps and model uncertainties in relative terms by comparing, for example, the relative richness of data between geographic areas or environmental media. As discussed in the proposal and more fully in the PA, from an uncertainty perspective, gaps in field measurement data increase uncertainties in modeled processes and in the specific application of such models. As noted above, processes that are embodied in an AAI-based standard are modeled using the CMAQ atmospheric model and steady-state ecological models. These models are characterized in the ISA as being well-established and have undergone extensive peer review. Nonetheless, the application of these models for purposes of specifying the factors in the AAI equation, on an ecoregion scale, is a new application that introduces uncertainties, especially in areas with limited observational data that can be used to evaluate this specific application. Understanding uncertainties in relevant modeled processes thus involves consideration of the uncertainties associated with applying each model as well as the combination of these uncertainties as the models are applied in combination within the AAI framework applied on an ecoregion scale.

Our confidence in improving critical load estimates can be increased by expanding water quality data bases used as inputs and evaluation metrics for critical load models. With regard to water quality data, the PA notes that such data are typically limited relative to air quality data sets, and are also relatively sparse in the western United States. While there are several state and local agency water quality data bases, it is unclear the extent to which differences in sampling, chemical analysis and reporting protocols would impact the use of such data for the purpose of better understanding the degree of protectiveness that would be afforded by an AAI-based standard within sensitive ecoregions across the country. In addition, our understanding of water quality in Alaska and Hawaii and the acid sensitivity of their ecoregions is particularly limited. Expanding the water quality data bases would enable clearer delineation of ecoregion representative critical loads in terms of the n^{th} percentile. This would provide more refined characterization of the degree of protection afforded by a given standard. Longer term, the availability of water quality trend data (annual to monthly sampled) would

support accountability assessments that examine if an ecoregion's response to air management efforts is as predicted by earlier model forecasting. The most obvious example is the long-term response of water quality ANC change to changes in calculated AAI, deposition, ambient NO_y and SO_x concentrations, and emissions. In addition, water quality trends data provide a basis for evaluating and improving the parameterizations of processes in critical load models applied at the ecoregion scale related to nitrogen retention and base cation supply. A better understanding of soil processes, especially in the southern Appalachians, would enhance efforts to examine the variability within ecoregions of the soil-based adsorption and exchange processes which moderate the supply of major cations and anions to surface waters and strongly influence the response of surface water ANC to changes in deposition of nitrogen and sulfur.

Steady-state biogeochemical ecosystem modeling is used to develop critical load estimates that are incorporated in the AAI equation through factor F1. Consequently, the PA notes that an estimate of the temporal response of surface water ANC to deposition and air concentration changes is not directly available. Lacking a predicted temporal response impairs the ability to conduct accountability assessments down to the effects level. Accountability assessments would examine the response of each step in the emissions source through air concentration—deposition—surface water quality—biota continuum. The steady-state assumption at the ecosystem level does not impair accountability assessments through the air concentration/deposition range of that continuum. However, in using steady-state ecosystem modeling, several assumptions are made relative to the long-term importance of processes related to soil adsorption of major ions and ecosystem nitrogen dynamics. Because these models often were developed and applied in glaciated areas with relatively thin and organically rich soils, their applicability is relatively more uncertain in areas such as those in the non-glaciated clay-based soil regions of the central Appalachians. Consequently, it is desirable to develop the information bases to drive simple dynamic ecosystem models that incorporate more detailed treatment of subsurface processes, such as adsorption and exchange processes and sulfate absorption.

B. CASAC Views

The CASAC has advised the EPA concerning the ISA, the REA, and the PA. The CASAC supported the EPA's interpretation of the science embodied in the ISA and the assessment approaches and conclusions incorporated in the REA.

Most recently, CASAC considered the information in the final PA in providing its recommendations on the review of the new multi-pollutant standard developed in that document and discussed above (Russell and Samet, 2011a). In so doing, CASAC expressed general support for the conceptual framework of the standard based on the underlying scientific information, as well as for the conclusions in the PA with regard to indicators, averaging time, form and level of the standard that are appropriate for consideration by the Agency in reaching decisions on the review of the secondary NAAQS for oxides of nitrogen and sulfur:

“The final *Policy Assessment* clearly sets out the basis for the recommended ranges for each of the four elements (indicator, averaging time, level and form) of a potential NAAQS that uses ambient air indicators to address the combined effects of oxides of nitrogen and oxides of sulfur on aquatic ecosystems, primarily streams and lakes. As requested in our previous letters, the *Policy Assessment* also describes the implications of choosing specific combinations of elements and provides numerous maps and tabular estimates of the spatial extent and degree of severity of NAAQS exceedances expected to result from possible combinations of the elements of the standard.”

“We believe this final PA is appropriate for use in determining a secondary standard to help protect aquatic ecosystems from acidifying deposition of oxides of sulfur and nitrogen. The EPA staff has done a commendable job developing the innovative Aquatic Acidification Index (AAI), which provides a framework for a national standard based on ambient concentrations that also takes into account regional differences in sensitivities of ecosystems across the country to effects of acidifying deposition.” (Russell and Samet, 2011a).

With respect to indicators, CASAC supported the use of SO_x and NO_y as ambient air indicators (discussed above in section III.A) and ANC as the ecological indicator (discussed above in section III.B.1). With respect to averaging time (discussed above in section III.C), CASAC agreed with the conclusions in the PA that “an averaging time of three to five years for the AAI parameters is appropriate.” CASAC noted that “a longer averaging time would mask possible trends of AAI, while a shorter averaging time would make the AAI being more influenced by the conditions of the

particular years selected” (Russell and Samet, 2011a).

With respect to the form of the standard (discussed above in section III.B), CASAC stated the following:

“EPA has developed the AAI, an innovative “form” of the NAAQS itself that incorporates the multi-pollutant, multi-media, environmentally modified, geographically variable nature of SO_x/NO_y deposition-related aquatic acidification effects. With the caveats noted below, CASAC believes that this form of the NAAQS as described in the final Policy Assessment is consistent with and directly reflective of current scientific understanding of effects of acidifying deposition on aquatic ecosystems.” (Russell and Samet, 2011a)

“CASAC agrees that the spatial components of the form in the Policy Assessment are reasonable and that use of Omernik’s ecoregions (Level III) is appropriate for a secondary NAAQS intended to protect the aquatic environment from acidification * * *

(Russell and Samet, 2011a).

The caveats noted by CASAC include a recognition of the importance of continuing to evaluate the performance of the CMAQ and ecological models to account for model uncertainties and to make the model-dependent factors in the AAI more transparent. In addition, CASAC noted that the role of DOC and its effects on ANC would benefit from further refinement and clarification (Russell and Samet, 2011a). While CASAC expressed the view that the “division of ecoregions into ‘sensitive’ and ‘non-sensitive’ subsets, with a more protective percentile applied to the sensitive areas, also seems reasonable” (Russell and Samet, 2011a), CASAC also noted that there was the need for greater clarity in specifying how appropriate screening criteria would be applied in assigning ecoregions to these categories. Further, CASAC identified potential biases in critical load calculations and in the regional representativeness of available water chemistry data, leading to the observation that a given percentile of the distribution of estimated critical loads may be protective of a higher percentage of surface waters in some regions (Russell and Samet, 2011a). Such potential biases led CASAC to recommend that “some attention be given to our residual concern that the available data may reflect the more sensitive water bodies and thus, the selection of the percentiles of waterbodies to be protected could be conservatively biased” (Russell and Samet, 2011a).

With respect to level as well as the combination of level and form as they are presented as alternative standards (discussed above in sections III.D–E), CASAC agreed with the PA conclusions

that consideration should be given to standard levels within the range of 20 and 75 µeq/L. CASAC also recognized that the level and the form of any AAI-based standard are so closely linked that these two elements should be considered together:

“When considered in isolation, it is difficult to evaluate the logic or implications of selecting from percentiles (70th to 90th) of the distribution of estimated critical loads for lakes in sensitive ecoregions to determine an acceptable amount of deposition for a given ecoregion. However, when these percentile ranges are combined with alternative levels within the staff-recommended ANC range of 20 to 75 microequivalents per liter (µeq/L), the results using the AAI point to the ecoregions across the country that would be expected to require additional protection from acidifying deposition. Reasonable choices were made in developing the form. The number of acid sensitive regions not likely to meet the standard will be affected both by choice of ANC level and the percentile of the distribution of critical loads for lakes to meet alternative ANC levels in each region. These combined recommendations provide the Administrator with a broad but reasonable range of minimally to substantially protective options for the standard.”

(Russell and Samet, 2011a).

CASAC also commented on the EPA’s uncertainty analysis, and provided advice on areas requiring further clarification in the proposed rule and future research. The CASAC found it “difficult to judge the adequacy of the uncertainty analysis performed by the EPA because of lack of details on data inputs and the methodology used, and lack of clarity in presentation” (Russell and Samet, 2011a). In particular, CASAC identified the need for more thorough model evaluations of critical load and atmospheric modeling, recognizing the important role of models as they are incorporated in the form of the standard. In light of the innovative nature of the standard developed in the PA, CASAC identified “a number of areas that should be the focus of further research” (Russell and Samet, 2011a). While CASAC recognized that the EPA staff was able to address some of the issues in the PA, they also noted areas “that would benefit from further study or consideration in potential revisions or modifications to the form of the standard.” Such research areas include “sulfur retention and mobilization in the soils, aluminum availability, soil versus water acidification and ecosystem recovery times.” Further, CASAC encouraged future efforts to monitor individual ambient nitrogen species, which would help inform further CMAQ evaluations and the

specification of model-derived elements in the AAI equation (Russell and Samet, 2011a).

C. Proposed Conclusions on Alternative Secondary Standards

As discussed in section III.H of the proposal, the Administrator considered whether it is appropriate at this time to set a new multi-pollutant standard to address deposition-related effects associated with oxides of nitrogen and sulfur, with a structure that would better reflect the available science regarding acidifying deposition to sensitive aquatic ecosystems. In so doing, she recognized that such a standard, for purposes of Section 109(b) and (d) of the CAA, must in her judgment be requisite to protect public welfare, such that it would be neither more nor less stringent than necessary for that purpose. In particular, she focused on the AAI-based standard developed in the PA and reviewed by CASAC, as discussed above. Based on consideration of the scientific basis for such a standard and the conclusions reached in the ISA, the Administrator agreed with the conclusion in the PA, and supported by CASAC, that there is a strong scientific basis for development of a standard with the general structure presented in the PA. She recognized that while the standard is innovative and unique, the structure of the standard is well-grounded in the science underlying the relationships between ambient concentrations of oxides of nitrogen and sulfur and the aquatic acidification related to deposition of nitrogen and sulfur associated with such ambient concentrations.

Nonetheless, the Administrator also recognized that such a standard would depend on atmospheric and ecological modeling, based on appropriate data, to specify the terms of an equation that incorporates the linkages between ambient concentrations, deposition, and aquatic acidification, for each separate ecoregion, and that there are a number of inherent uncertainties and complexities that are relevant to the question of whether it is appropriate under Section 109 of the CAA to set a specific AAI-based standard at this time. Based on her consideration of these important uncertainties and limitations, the Administrator recognized that in combination, these limitations and uncertainties result in a considerable degree of uncertainty as to how well the quantified elements of the AAI standard would predict the actual relationship between varying ambient concentrations of oxides of nitrogen and sulfur and steady-state ANC levels across the distribution of water bodies within the

various ecoregions in the United States. Because of this, there is considerable uncertainty as to the actual degree of protectiveness that such a standard would provide, especially for acid-sensitive ecoregions. The Administrator recognized that the AAI equation, with factors quantified in the ranges discussed above and described more fully in the PA, generally performs well in identifying areas of the country that are sensitive to such acidifying deposition and indicates, as expected, that lower ambient levels of oxides of nitrogen and sulfur would lead to higher calculated AAI values. However, the uncertainties discussed here are critical for determining the actual degree of protection that would be afforded such areas by any specific target ANC level and percentile of water bodies that would be chosen in setting a new AAI-based standard, and thus for determining an appropriate AAI-based standard that meets the requirements of Section 109.

The Administrator noted that setting a NAAQS generally involves consideration of the degree of uncertainties in the science and other information, such as gaps in the relevant data and, in this case, limitations in the evaluation of the application of relevant ecological and atmospheric models at an ecoregion scale. She noted that the issue here is not a question of uncertainties about the scientific soundness of the structure of the AAI, but instead uncertainties in the quantification and representativeness of the elements of the AAI as they vary in ecoregions across the country. At present, these uncertainties prevent an understanding of the degree of protectiveness that would be afforded to various ecoregions across the country by a new standard defined in terms of a specific nationwide target ANC level and a specific percentile of water bodies for acid-sensitive ecoregions and thus prevent identification of an appropriate standard.

The Administrator judged that the uncertainties are of such nature and magnitude that there is no reasoned way to choose a specific AAI-based standard, in terms of a specific nationwide target ANC level or percentile of water bodies that would appropriately account for the uncertainties, since neither the direction nor the magnitude of change from the target level and percentile that would otherwise be chosen can reasonably be ascertained at this time. Further, she noted that CASAC acknowledged that important uncertainties remain that would benefit from further study and data collection efforts, which might lead to potential revisions or modifications

to the form of the standard developed in the PA, and that CASAC encouraged the Agency to engage in future monitoring and model evaluation efforts to help inform further development of the elements of an AAI-based standard. Based on these considerations the Administrator judged that the current limitations in relevant data and the uncertainties associated with specifying the elements of the AAI based on modeled factors are of such nature and degree as to prevent her from reaching a reasoned decision such that she is adequately confident as to what level and form (in terms of a selected percentile) of such a standard would provide any particular intended degree of protection of public welfare that the Administrator determined satisfied the requirements to set an appropriate standard under Section 109 of the CAA.

Based on the above considerations, the Administrator provisionally concluded that it is premature to set a new, multi-pollutant secondary standard for oxides of nitrogen and sulfur at this time, and as such she proposed not to set such a new secondary standard. Nonetheless, while the Administrator concluded that it is premature to set such a multi-pollutant standard at this time, she determined that the Agency should undertake a field pilot program to gather additional data (discussed below in section IV). She concluded that it is appropriate that such a program be undertaken before, rather than after, reaching a decision to set such a standard.

In reaching her proposed decision not to set a new AAI-based standard at this time, the Administrator recognized that the new NO₂ and SO₂ primary 1-hour standards set in 2010, while not ecologically relevant for a secondary standard, will nonetheless result in reductions in oxides of nitrogen and sulfur that will directionally benefit the environment by reducing NO_y and SO_x deposition to sensitive ecosystems. The Administrator proposed to revise the secondary standards by adding secondary standards identical to the NO₂ and SO₂ primary 1-hour standards set in 2010, including a 1-hour secondary NO₂ standard set at a level of 100 ppb and a 1-hour secondary SO₂ standard set at a level of 75 ppb. The EPA noted that while this will not add secondary standards of an ecologically relevant form to address deposition-related effects, it will provide additional protection for sensitive areas. The EPA further noted that this proposed decision is consistent with the view that the current secondary standards are neither sufficiently protective nor appropriate in form, but that it is not

appropriate to propose to set a new, ecologically relevant multi-pollutant secondary standard at this time, for the reasons summarized above.

The EPA solicited comment on all aspects of this proposed decision, as discussed in the following section.

D. Comments on Alternative Secondary Standards

In this section, comments received on the proposal related to an AAI-based standard are discussed in section III.D.1 and comments related to the proposed decision to set 1-hour NO₂ and SO₂ secondary standards are discussed in section III.D.2.

1. Comments Related to an AAI-Based Standard

General comments that either supported or opposed the proposed decision not to set an AAI-based standard in this review are addressed in this section. Two groups of commenters offered sharply divergent views on whether it is appropriate for the EPA to set or even consider an AAI-based standard to protect against the effects in aquatic ecosystems from acidifying deposition associated with ambient concentrations of oxides of nitrogen and sulfur. These groups provided strongly contrasting views on the strength and limitations in the underlying scientific information upon which such a standard could be based, as well as on the legal authority and requirements in the CAA for the EPA to set such a standard. These comments are discussed below in section III.D.1.a, and build in part on the overarching issue raised by some commenters as to the EPA's authority under the CAA to include deposition-related effects within the scope of a NAAQS review, which is discussed above in section I.E. Some commenters also expressed views about specific aspects of an AAI-based approach, as discussed below in section III.D.1.b. More technical comments on specific elements and factors of the AAI are discussed in the Response to Comments document. General comments based on implementation-related factors that are not a permissible basis for considering an alternative standard are noted in the Response to Comments document.

a. Comments on Consideration of an AAI-Based Standard

The first group of commenters, including several industry groups (e.g., EPRI, UARG, and API), individual companies (e.g., East Kentucky Power Cooperative), and two states (TX, SD), strongly supported the EPA's proposed decision not to set an AAI-based

standard in this review. These commenters generally focused on the limitations and uncertainties in the scientific evidence used by the EPA as a basis for its consideration of an AAI-based standard, expressing the view that these limitations and uncertainties were so great as to preclude setting such a standard at this time. Several industry commenters felt the uncertainties were of sufficient magnitude as to invalidate the AAI approach for use in the NAAQS, while others agreed with the EPA's finding that further information and analysis is needed, and further noted that this work should be completed before the EPA could propose a new multi-pollutant standard. More fundamentally, some commenters in this group expressed the view that any consideration of such a standard is inconsistent with various provisions of the CAA and thus unlawful.

With regard to their views on the underlying scientific information, many of these commenters focused on what they asserted were areas of substantial uncertainty in the AAI approach including uncertainties in the individual F factors of the AAI, air deposition modeling, critical loads modeling, and available water quality and watershed data. Several commenters felt a more rigorous uncertainty and variability analysis of the AAI, beyond the analyses that the EPA presented in the PA, would be needed if the EPA were to consider such a standard in the future.

Some commenters expressed concerns with specific aspects of the AAI, such as the adequacy of the Omernik ecoregion approach as a method of waterbody aggregation for critical load calculations and whether ANC was an appropriate ecological indicator. The commenters asserted that the EPA needed to explore different methods for calculating critical loads, collect essential data, and employ mechanistic water chemistry models. The commenters also felt that the EPA was arbitrary in choosing its criteria for sensitive ecoregions and percent waterbodies, and that there was a bias in the field data toward sensitive areas. Several commenters felt a more comprehensive research program was needed to improve characterization of the biogeochemical and deposition processes incorporated into the AAI.

Some industry groups commented on uncertainties in the CMAQ modeling, including high levels of uncertainty surrounding measurement and modeling of chemically reduced forms of nitrogen (NH_x). Other commenters were also critical of the reliance of the AAI on modeling, and expressed the

view that CMAQ would require intensive deposition-focused evaluation.

A second group of commenters, including several environmental groups (e.g., Center for Biological Diversity, Earthjustice, and Adirondack Council), the U.S. Department of Interior and the National Park Service, the New York Department of Environmental Conservation, and two tribes (Fond du Lac Band and Potawatomi) strongly disagreed with the EPA's proposed decision not to set an AAI-based standard in this review. These commenters generally focused on the strengths of the evidence of deposition-related effects, the extent to which analyses presented in the PA addressed uncertainties and limitations in the evidence, and on information regarding the adversity of such effects as a basis for their views that such a standard was warranted at this time. Many of these commenters pointed to CASAC's review of the underlying scientific evidence and its support for moving forward with an AAI-based standard at this time as support for their views.

In general, the environmental group commenters expressed the view that the current standards are clearly not adequate and that a combined NO_x/SO_x standard that links ambient air quality to an ecosystem indicator is appropriate, founded in science, and necessary for protection of public welfare. The commenters stated the current standards are neither sufficiently protective nor appropriate to address deposition-related effects. They also noted that the EPA has worked for decades to solve the acid deposition problem and that in their view the AAI represents an elegant solution to that problem.

With regard to their views on the underlying scientific information, these commenters generally agreed with the EPA's proposed conclusions that there are well-established water quality and biological indicators of aquatic deposition and well-established models that address air deposition, water quality impacts, and effects on biota. Many of these commenters expressed the view that the uncertainties and limitations in the scientific evidence were adequately addressed in the PA, which was reviewed by CASAC. Many of these commenters pointed to CASAC's support for adopting an AAI-based standard in this review while concurrently conducting additional field monitoring and longer-term research that might reduce uncertainties in future reviews of secondary NAAQS for oxides of nitrogen and sulfur.

Some governmental agency commenters were strongly supportive of an AAI-based standard and clearly felt

such a standard should be adopted now. They also noted that the current ambient concentrations of NO_x and SO_x are causing adverse ecological impacts and they believe that ongoing damage due to acidic deposition and the risks to ecosystems far outweigh the risk of setting an AAI-based standard while some uncertainties remain. They assert that NO_x and SO_x deposition is causing adversity to public welfare and that the scientific uncertainties do not preclude setting an AAI-based standard, and point to CASAC as generally supporting this view. The commenters believe that the EPA has ample evidence to support a new ecologically based standard and that the AAI is reasonable and scientifically defensible. NY specifically recommended an AAI of 50 with some flexibility built into the F factors.

Some of these agency and environmental group commenters also referenced CASAC's support for specific elements of the AAI-based standard developed in the PA, including (1) The use of ANC as an appropriate ecological indicator for such a standard, (2) the use of NO_y and SO_x as well-justified indicators of atmospheric concentrations of oxides of nitrogen and sulfur, (3) the use of Omernik Level III ecoregions, (4) the division of ecoregions into sensitive and non-sensitive categories, (5) the use of a 3 to 5 year averaging time, and (6) the appropriateness of an AAI level between 20 to 75 $\mu\text{eq/L}$.

With regard to their views on the requirements of the CAA, several environmental group commenters stated that given the large body of evidence supporting significant ongoing harm to the public welfare and the EPA's finding the current standards are neither sufficiently protective nor appropriate to address deposition-related effects, the EPA's reliance on uncertainty as grounds for failing to propose protective standards is irrational, arbitrary, and legally flawed. They believe that the EPA cannot lawfully reject a new AAI-based standard while continuing to rely solely on a form of the standard that is inadequate and allows serious harms to the public welfare to continue. When confronted with scientific uncertainties and incomplete data, they feel the EPA must act in a precautionary manner that errs toward stronger protections. Further, they believe that the EPA's reliance on scientific uncertainty as a basis for its inaction is unsupportable in light of CASAC's advice and the EPA staff's conclusions in the ISA, REA and PA.

In addition to the two broad groups of commenters discussed above, a few other commenters offered more general

views on an AAI-based standard. For example, some state commenters (NC and PA) expressed support for the concept of developing a multi-pollutant, AAI-based standard, but felt that it would be important to gather additional information before proposing any such standard. One state organization (NESCAUM) expressed concern that the EPA was not following CASAC's recommendation to propose an ecologically relevant level and form for this NAAQS.

The EPA has carefully considered these comments on whether or not an AAI-based secondary standard for oxides of nitrogen and sulfur is appropriate at this time. The EPA agrees with the second group of commenters and CASAC's advice (outlined in section III.B) that there is a strong scientific basis for development of the structure of such a standard, specifically with regard to a standard that would provide protection from deposition-related aquatic acidification in sensitive ecosystems across the country. As discussed in section II.A and supported by several commenters, the available scientific evidence is sufficient to infer a causal relationship between acidifying deposition of nitrogen and sulfur and potential adverse effects to aquatic ecosystems, and that the deposition of oxides of nitrogen and sulfur both cause such acidification under current conditions that are allowed by the current secondary standards (U.S. EPA, 2008, chapter 3). The EPA agrees with commenters that there are well-established water quality and biological indicators of aquatic acidification as well as well-established models that address deposition, water quality, and effects on ecosystem biota, and that ecosystem sensitivity to acidification varies across the country (U.S. EPA, 2011, chapter 7).

The EPA also agrees with the second group of commenters and CASAC that ANC would be an appropriate ecological indicator, reflecting the acidifying effects of deposition of nitrogen and sulfur (U.S. EPA, 2011, chapter 7.2 and Russell and Samet, 2011a). Further, the EPA agrees that the structure of an AAI-based standard is well-grounded in science and would address the combined effects of deposition from oxides of nitrogen and sulfur by characterizing the linkages between ambient concentrations, deposition, and aquatic acidification, and that the structure of the standard takes into account relevant variations in these linkages across the country (section III.B. above and U.S. EPA, 2011, chapter 7).

The EPA disagrees with the first group of commenters that the use of Omernik ecoregions would be inadequate. A full explanation of the EPA's rationale for selecting the Omernik ecoregion scheme for spatial aggregation is found in section 7.2.5 of the PA. Omernik ecoregions include consideration of geology, physiology, vegetation, climate, soils, land use, wildlife, and hydrology. These factors also relate well to sensitivity to acidification. The EPA also evaluated the National Ecological Observatory Network (NEON) and Bailey's ecoregions developed for the U.S. Forest Service and concluded that the Omernik ecoregion classification would be the most appropriate for an AAI-based standard. It offers several levels of spatial delineation, has undergone extensive scientific peer review, and has explicitly been applied to delineating acid sensitive areas of the U.S.

Nonetheless, the EPA agrees with the first group of commenters that there are important and significant remaining scientific uncertainties within the derivation of the AAI, with the data used to specify the factors within the AAI equation, and with the models themselves. These uncertainties are more fully discussed in Appendix F and G of the PA and in section III.A.5 above. These uncertainties have been reviewed by CASAC, and the EPA recognizes that further research would help to reduce the uncertainties. In general, the EPA also recognizes that the AAI would depend on atmospheric and ecological modeling, with inherent uncertainties, to specify the terms of an AAI equation that incorporate the linkages between ambient concentrations, deposition, and aquatic acidification.

The EPA agrees with the first group of commenters that there are several important limitations in the available data upon which elements of the AAI are based (U.S. EPA, 2011, Chapter 7). For example, existing monitors for NO_y are generally not located in areas that are representative of sensitive aquatic ecosystems, and there is relatively sparse water quality data coverage in sensitive mountainous western areas. Further, even in areas where relevant data are available, small sample sizes impede efforts to characterize the representativeness of the available data for some ecoregions, which was noted by CASAC as being of particular concern (Russell and Samet, 2011a). Also, measurements of reduced forms of nitrogen are available from only a small number of monitoring sites, and emission inventories for reduced forms of nitrogen used in atmospheric

modeling are subject to a high degree of uncertainty.

The EPA agrees with the first group of commenters that uncertainties related to the use of ecological and atmospheric models are difficult to evaluate due to a lack of relevant observational data. For example, relatively large uncertainties are introduced by a lack of data with regard to pre-industrial environmental conditions and other parameters that are necessary inputs to critical load models that are the basis for factor F1 in the AAI equation. Also, observational data are not generally available to evaluate the modeled relationships between nitrogen and sulfur in the ambient air and associated deposition, which are the basis for the other factors (i.e., F2, F3, and F4) in the AAI equation. The EPA recognizes that, in contrast, such model-related uncertainties are not relevant in the consideration of other NAAQS since those NAAQS are not defined in terms of factors based on such models.

The EPA agrees that these data limitations and model uncertainties create a number of inherent uncertainties and complexities in the quantification of the F factors of the AAI and the representativeness of the F factors at an ecoregion scale (U.S. EPA, 2011, Appendix F). These uncertainties and complexities currently lead to a high degree of uncertainty in characterizing the degree of protectiveness that would be afforded by an AAI-based standard with quantified F factors derived as discussed above, within the ranges of levels and forms identified in section III.A above.

The EPA disagrees with the first set of commenters that the selection of sensitive ecoregions and percentile waterbodies would be arbitrary. The EPA fully discussed its rationale and selection of sensitive ecoregions and the range of percentiles used in section 7.2.5 of the PA. The EPA relied on available alkalinity and ANC data to draw distinctions between sensitive and non-sensitive ecoregions. The EPA used its judgment in selecting the range of percentiles for sensitive and non-sensitive ecoregions, attempting to be neither over-protective nor under-protective of the set of waterbodies in each ecoregion.

In general, the first set of commenters tends to treat all aspects of the AAI as subject to a high to very high degree of uncertainty. The EPA disagrees with this view, and instead views some parts of the AAI as based on more certain scientific information than others. For example, the EPA believes there is a solid scientific basis for the general

framework of the AAI and for the relationship between ANC and effects on aquatic life. There is a strong basis for selection of ANC as an ecological indicator, for selection of NO_y and SO_x as ambient air indicators, for selection of the annual and 3- to 5-year averaging time frame, and for selection of the range of ANC and percentile of water bodies for consideration. Likewise, the EPA believes there is a solid scientific basis for selection of Omernik ecoregions as the geographic basis for development of the AAI F factors. The EPA believes that for many areas there is a strong basis for determining whether an ecoregion is acid sensitive or not acid sensitive, while recognizing there is some uncertainty in some areas as to which category the area should fall in. The EPA's decision not to adopt an AAI-based standard at this time is not driven by uncertainty in these elements of the AAI, but instead in the elements needed to derive the quantified F factors for ecoregions across the country and our ability to evaluate the representativeness of those F factors for an entire ecoregion. The greatest uncertainties concern the F1 and F2 factors, which relate to development of a single critical load to represent a specified percentile of all of the waterbodies in an ecoregion and development of the value for deposition of reduced nitrogen. In addition, there are also important and significant uncertainties related to development of the F3 and F4 factors, which concern the quantified relationship between ambient levels of NO_y and SO_x and deposition rates of nitrogen and sulfur. The bases for these uncertainties are discussed in more detail in sections III.A.5 above and are considered as well in section III.E below. Thus, while the EPA agrees in part with the first group of commenters, in general they paint with too broad a brush. The EPA's decision is based instead on taking into account the areas where there is less scientific uncertainty as well as the areas where there remain significant scientific uncertainties.

In general, the second set of commenters does not contest the scientific evidence as discussed by the EPA or the scientific conclusions the EPA draws. They do not contest the existence of scientific uncertainty or the causes of it, and do not present scientific or technical arguments to contest the nature or magnitude of the uncertainty. Instead, they disagree with the conclusions or judgments to draw from the uncertainty. In the view of these commenters, the degree of uncertainty is low enough to warrant

setting an AAI standard at this time. They disagree with the Administrator's policy judgment that the nature and magnitude of uncertainty is of such significance that it warrants not setting an AAI standard at this time. Their primary disagreement is with this judgment, not with the EPA's underlying views on the science and its uncertainties. As discussed in the proposal and below, however, the Administrator's reasoned judgment is that it is not appropriate to establish an AAI-based secondary standard at this time. The uncertainties discussed above prevent a reasoned understanding of the degree of protectiveness that would be afforded to various ecoregions across the country by a new standard defined in terms of a specific nationwide target ANC level and a specific percentile of water bodies for acid-sensitive ecoregions. Therefore, the Administrator is unable to identify an appropriate standard.

The EPA recognizes that the AAI equation, with factors quantified in the ranges discussed in section III.A above and described more fully in chapter 7 of the PA, generally performs well in identifying areas of the country that are sensitive to such acidifying deposition and indicates, as expected, that lower ambient levels of oxides of nitrogen and sulfur would lead to higher calculated AAI values (PA, chapter 7). However, the various uncertainties discussed above are critical for determining with any degree of confidence the actual degree of protection that would be afforded such areas by any specific target ANC level and percentile of water bodies that would be chosen in setting a new AAI-based standard with quantified F factors, and thus for determining an appropriate AAI-based standard that meets the requirements of Section 109 of the CAA. The EPA recognizes that these limitations and uncertainties result in a high degree of uncertainty as to how well the quantified elements of the AAI standard would predict the actual relationship between varying ambient concentrations of oxides of nitrogen and sulfur and steady-state ANC levels across the distribution of water bodies within the various ecoregions in the United States. Because of this, there is a high degree of uncertainty as to the actual degree of protectiveness that such a standard would provide, especially for acid-sensitive ecoregions.

With regard to comments that the EPA cannot lawfully reject a new AAI-based standard, the EPA disagrees with the second group of commenters that the Administrator is required to set an AAI-based standard at this time. Although

the Administrator has concluded that the current secondary standards are neither appropriate nor adequate to protect against potentially adverse deposition-related effects associated with ambient concentrations of oxides of nitrogen and sulfur, such a conclusion does not require the EPA to adopt a new NAAQS where the Administrator cannot reasonably judge that it would meet the criteria for a secondary NAAQS.

The Administrator judges that the current limitations in relevant data and the uncertainties associated with specifying the elements of a new AAI-based NAAQS defined in terms of modeled factors are of such a significant nature and degree as to prevent her from reaching a reasoned decision as to what level and form (in terms of a selected percentile) of such a standard would provide any particular intended degree of protection of public welfare that the Administrator determined satisfied the requirements to set an appropriate standard under Section 109 of the CAA. As a result, the Administrator has determined that she cannot establish an AAI-based standard that is requisite to protect public welfare. The Administrator has made a similar judgment in deciding not to adopt new secondary NAAQS in the form of 1-hour standards identical to the primary NO₂ and SO₂ standards, as discussed below. No other NAAQS revisions to address the effects of acid deposition associated with oxides of nitrogen and sulfur in the ambient air have been suggested or considered by the EPA, CASAC, or commenters in this review.¹³ As such, all possible revisions to the secondary NAAQS to address the effects of acid deposition would involve adoption of new secondary standards that are judged by the Administrator to have such a high degree of uncertainty that she cannot make a reasoned decision that a new standard would satisfy the criteria of Section 109(b) of the CAA.

Commenters have pointed to the requirement in Section 109(b)(2) of the CAA that any secondary NAAQS "must specify a level of air quality the attainment and maintenance of which * * * is requisite to protect the public welfare from any known or anticipated adverse effects * * *" in support of the argument that the EPA must adopt a new standard that provides requisite protection, having concluded that the

¹³ No one has suggested that the EPA should revise the current 3-hour or annual secondary standards to address the effects of acidifying deposition associated with oxides of nitrogen and sulfur in the ambient air. All revisions under consideration have involved adopting new secondary NAAQS.

current secondary standards are not sufficient to protect against adverse effects. In considering this comment, the EPA has taken into account the statutory language, as well as the bases for the EPA's conclusion that the current standards for oxides of nitrogen and sulfur are neither appropriate nor adequate to provide protection against potentially adverse deposition-related effects and the data and model uncertainties that limit our efforts to characterize the degree of protectiveness that would be afforded by either an AAI-based standard or a 1-hour standard. We have concluded that Section 109 of the CAA does not require the EPA to adopt a new secondary standard where, as here, in the reasoned judgment of the Administrator, the uncertainties associated with such a standard are of such significance that they prevent her from determining whether or not such a NAAQS is requisite to protect public welfare. Section 109(b) of the CAA does not require the EPA to set a new standard under circumstances where the Administrator cannot reasonably judge that it would meet the criteria for a secondary NAAQS.

This is consistent with the decision by the Supreme Court in *Massachusetts v. EPA*, 549 U.S. 497 (2007), which concerned the EPA's authority under Section 202(a) of the CAA. There the Supreme Court determined that "is so profound that it precludes the EPA from making a reasoned judgment" concerning endangerment to public health and welfare from air pollution would justify the EPA not making a finding on endangerment. Id. at 534. The Court noted that "[t]he statutory question is whether sufficient information exists to make" an endangerment finding. Id. In this review, the scientific uncertainty is of such a significant nature and degree that sufficient information does not exist for the EPA to make a reasoned judgment as to whether a new secondary standard addressing aquatic acidification would satisfy the criteria of Section 109(b). As such, adding a new AAI secondary standard at this time would not "be appropriate under [Section 109(b)]." CAA Section 109(d)(1).

The EPA recognizes and agrees with the comment from one environmental group that the EPA is not "foreclosed from setting a standard unless it can identify * * * a 'perfect' standard level that is free from any noteworthy uncertainty." However, that is not the situation in this rulemaking. The Agency has concluded that it would not be appropriate to promulgate a standard to address the public welfare effects of

acidifying deposition where the remaining scientific uncertainties are of such significance that they preclude the EPA from making a reasoned determination of the degree of protectiveness that would be afforded by such a standard. The EPA recognizes that as a result of not setting a new secondary standard the current secondary standards continue in place and continue to be neither appropriate nor adequate to protect against potentially adverse deposition-related effects associated with ambient concentrations of oxides of nitrogen and sulfur. However, in the Administrator's view the proper response under the current circumstances is to continue to develop the scientific and technical basis for a future revision to the standards, and not to adopt at this time a new secondary standard that she cannot reasonably judge would comply with Section 109 of the CAA.

Further, the EPA agrees with both groups of commenters and CASAC that collecting further field data would be beneficial. A field pilot program is discussed in detail in section IV below. However, the EPA disagrees with the first group of commenters' assertions that these uncertainties should invalidate or preclude the further development of an AAI-based standard.

b. Comments on Specific Aspects of an AAI-Based Approach

This section discusses comments on the following four specific aspects of an AAI-based approach to setting a secondary standard for oxides of nitrogen and sulfur: (1) The inclusion of chemically reduced nitrogen (NH_x), in addition to oxides of nitrogen, in the AAI equation; (2) whether such a standard would be appropriately construed as a national standard versus a regional standard; (3) whether such a standard would be appropriately construed as an ambient air quality standard versus a water quality standard, and (4) whether the EPA has authority under the CAA to set a multi-pollutant NAAQS.

(1) As described above in section III.A, the AAI equation contains a separate factor that accounts for the acidifying potential of NH_x , in addition to the factor that accounts for the acidifying potential of oxides of nitrogen. Several industry commenters addressed this issue explicitly, with some expressing the view that NH_x should be treated the same as NO_x in the AAI, while others felt it should not be included at all in the AAI. Several commenters expressed the view that accounting for NH_x in the AAI equation represents a *de facto* regulation of

ammonia, which they assert is unlawful since reduced nitrogen is not a listed air pollutant under Section 108 of the CAA.

Other commenters, including environmental groups and governmental agency commenters, did not explicitly comment on the inclusion of NH_x in the AAI equation; however several commenters made note of CASAC's advice on this issue. CASAC advised that it is necessary to include a factor for NH_x in the AAI equation, even though it is not a listed pollutant, since aquatic ecosystems respond to inputs of NH_x to create acidity just like they do with inputs of NO_x and SO_x .

The EPA has included NH_x deposition explicitly as part of factor F2 in the AAI expression to account for the acidifying potential afforded by ammonia gas and ammonium ion. Inclusion of NH_x deposition, in addition to deposition of oxides of nitrogen, is necessary to account for potential effects of all reactive nitrogen species which, in turn, allows for determining the contributions of oxides of N and S to aquatic acidification. This approach is consistent with the requirement in the CAA that where the state of the science provides a basis for considering such effects, the review of the air quality criteria for a pollutant should encompass the ways in which other air pollutants may interact with the criteria pollutant to produce adverse effects. See CAA Section 108(a)(2). In effect, the inclusion of NH_x deposition can be viewed as a necessary component consistent with our scientific understanding that links deposition of all nitrogen species to ecological effects.

The EPA recognizes that the NAAQS is established to address the pollutants oxides of nitrogen and oxides of sulfur. Consequently, the ambient concentrations of oxides of sulfur (as SO_x) and nitrogen (as NO_x) are accounted for separately from the deposition of NH_x in the AAI equation, thus defining the standard specifically in terms of the acidifying potential of levels of oxides of nitrogen and sulfur in the ambient air. More specifically, compliance with an AAI-based standard would be based on using federal reference or equivalent monitoring methods to measure ambient concentrations of NO_y and SO_x to determine an area's attainment status. Conversely, there would be no requirement to measure concentrations of NH_x to determine compliance with an AAI-based standard. Rather, ecoregion-specific values of NH_x deposition would be determined by modeling and would be specified by the EPA in conjunction with setting such a

standard, and would not be a variable in the AAI equation as would SO_x and NO_y . The contribution of reduced forms of nitrogen to total nitrogen deposition would represent an ecosystem-specific environmental factor that plays a necessary background role in characterizing the relationship between the measured, variable levels of the ambient air indicators of oxides of nitrogen and sulfur (NO_y and SO_x) and the associated degree of aquatic acidification. Section 108 requires the air quality criteria to evaluate to the extent practicable the variable factors such as atmospheric conditions that affect the impact of the ambient air pollutant (in this case oxides of nitrogen and sulfur) on the public welfare. In this review, such variable factors include the deposition of reduced nitrogen in an ecoregion, as well as all of the other elements reflected in the factors F1 to F4, and the designation of an area as acid-sensitive or not acid-sensitive. Section 109 calls for the EPA to base the NAAQS on the air quality criteria, and accounting for the role of reduced nitrogen deposition in the AAI reflects this.

In considering this aspect of an AAI-based standard, the EPA took into account that in applying the AAI equation, all factors, including NH_x deposition, would be updated as appropriate as part of the periodic reviews of the NAAQS, called for at five-year intervals by the CAA, to account for changing environmental conditions and new data. In determining an ecoregion's status with regard to meeting a particular AAI-based standard, NH_x deposition reflected in the F2 factor would be treated just as all of the other environmental terms—e.g. critical loads and transference ratios—which influence factors F1, F3 and F4. To the extent that changes in NH_x deposition occur from one review to the next, the ecoregion-specific F2 factors would be updated to reflect such changes. To the extent that NH_x deposition decreased from one review to the next, an AAI-based standard updated during a periodic review to reflect this change would allow for potentially higher levels of NO_y and SO_x that would meet a specific AAI-based standard; conversely, increased levels of NH_x deposition would allow for potentially lower levels of NO_y and SO_x . Meeting a specific AAI-based standard would only require that the combined levels of NO_y and SO_x be such that a calculated AAI value meet or exceed the AAI value set as the level of the standard. Consequently, while the contribution of NH_x deposition would

be accounted for, NH_x emissions would not be regulated through the implementation of an AAI-based standard. NH_x deposition would be treated as an ecologically relevant background value that could be updated over time to reflect changes in circumstances, but accounting for such changes would not be required for purposes of determining compliance with an AAI-based standard. Thus, the incorporation of NH_x in the AAI equation would not result in *de facto* regulation of NH_x emissions.

(2) Some commenters raised the issue of whether an AAI-based standard would be a national standard, as required by Section 109 of the CAA, or whether it is in essence a regional standard. One group of commenters (the Center for Biological Diversity and the National Park Service) generally expressed the view that an AAI-based standard would be a national standard, whereas another group, including industry commenters, asserted that an AAI-based standard would be a regional standard and thus not consistent with the requirements of the CAA.

The first group of commenters supported the use of a national ANC indicator, recognizing that an AAI approach would account for regional differences in sensitivity and relevant environmental factors while providing a nationally consistent degree of protection across sensitive ecoregions. For example, the National Park Service stated that the AAI approach provides a uniform level of protection to sensitive ecosystems while appropriately taking into account the variability in deposition, meteorology, and other relevant environmental factors across ecoregions.

The second group of commenters noted that application of the AAI equation in different areas of the country produced different allowable concentrations of NO_y and SO_x , asserting as a result that an AAI-based standard would be a regional standard. These commenters asserted that the EPA lacks authority under the CAA to set such a regional NAAQS. For example, UARG states that the AAI is applied differently in different regions of the country (e.g., sensitive vs. non-sensitive ecoregions). The Alliance of Automobile Manufacturers commented that both the EPA and Congress historically have decided that secondary national air quality standards are not an appropriate approach to address regionally variable welfare effects.

The EPA believes that a secondary NAAQS based on the AAI approach could be a national standard, consistent with the CAA. An AAI-based standard

would apply all across the country. It would be defined in part by a single level of the AAI—that is, every part of the country would be expected to meet or exceed a specified AAI level. The scientific basis for setting a national AAI level is rooted in the similarity between AAI and acid neutralizing capacity (ANC), which is a widely accepted ecological health indicator for aquatic acidification. The rationale underlying the use of ANC is that the ecosystem health reflected by an ANC value in one part of the country is generally similar to that in another location, irrespective of regional differences in biogeochemistry and atmospheric conditions. The EPA recognizes that allowable concentrations of the ambient air pollutant indicators for oxides of nitrogen and sulfur in the AAI equation can vary from one location to another and result in the same calculated AAI. The difference between an AAI-based standard and the existing primary standards is that the level of the standard is defined directly in terms of the measured ambient air pollutant indicator. That is, the health-based indicator and the measured ambient air indicator are based on the same chemical entity. In an AAI-based standard, the level of the standard, reflecting a nationally consistent degree of protection, would be defined in terms of an ecological indicator, ANC, and compliance would be determined based on concentrations of the ambient air indicators, NO_y and SO_x . From an ecosystem health perspective, it is most relevant to use the ecological indicator, ANC, to establish a single level that, in the context of an AAI, leads to a similar degree of protection across the country. The allowable levels of NO_y and SO_x could vary across the country, while the specified AAI level and the corresponding degree of protection, would not. This would facilitate ensuring that such a NAAQS would provide sufficient protection, but not more than was necessary. It should be noted that in the 2006 PM NAAQS decision the EPA set a NAAQS that envisions variation in allowable ambient levels of certain kinds of PM. The EPA set a PM_{10} standard with a single numerical level, which then allowed varying levels of coarse PM, a subset of PM_{10} . The PM_{10} standard was designed to allow lower levels of coarse PM in urban areas and higher levels of coarse PM in non-urban, rural areas. The EPA's goal was to target protection at urban areas, where the evidence showed coarse particles presented a greater risk to public health. The single numerical standard for PM_{10} allowed

variable levels of coarse PM, with higher allowable levels where there was less evidence of risk and lower allowable levels where the evidence of risk was greater. This approach was upheld in *American Farm Bur. Fed. v. EPA*, 559 F.3d 512, 533–536 (D.C. Cir. 2009).

In conjunction with consideration of an AAI-based standard, the EPA has recognized that the nation includes some relatively acid-sensitive and some relatively non-acid sensitive ecoregions. This delineation allows for an appropriate application of the AAI equation that increases its relevancy from a national perspective as it avoids creating more than requisite protection in areas that are not acid sensitive. The AAI equation and the selected level of such a standard would be applicable everywhere; however, factors in the AAI equation are appropriately dependent on the sensitive and non-sensitive ecoregion classification. Therefore, the delineation of sensitive and non-sensitive regions allows for a nationally consistent application of the AAI equation as it targets protection on those areas most likely to benefit from reductions in acidifying deposition of oxides of nitrogen and sulfur, and avoids more than requisite protection in areas that would not benefit from such reductions.

(3) Some commenters expressed the view that an AAI-based standard would essentially be a water quality standard, since it would use ANC, a water quality property, as the ecological indicator. For example, UARG expressed this view by noting that an AAI standard would be defined in terms of a single water quality level with multiple allowable air quality concentrations of oxides of nitrogen and sulfur.

The EPA notes that the AAI relates aquatic acidification to ambient air concentrations of oxides of nitrogen and sulfur. An AAI-based standard would be set at a level such that ambient air concentrations would not cause harmful acidification effects to water quality resources, which is within the scope of welfare effects that secondary NAAQS are to address (i.e., welfare effects include, but are not limited to, “effects on soils, water, * * *”). Accordingly, while an AAI-based standard would address effects on water quality, it would do so by defining the allowable ambient air concentrations of oxides of nitrogen and sulfur that would provide appropriate protection against such effects. Compliance with such a standard would be determined by measuring ambient air concentrations of NO_y and SO_x, not by measuring the water quality property of ANC. The actual water quality of any body of

water would not be used to determine compliance with the air quality standard, and no body of water would be considered in “non-compliance” with an AAI air quality standard. Thus, an AAI-based standard is appropriately construed as an air quality standard, not a water quality standard.

(4) Some commenters questioned whether the EPA has the authority to establish a NAAQS that jointly addresses ambient concentrations of oxides of nitrogen and oxides of sulfur. Pointing to language in Section 109(b)(2) that a NAAQS must address “adverse effects associated with the presence of *such air pollutant* in the ambient air,” these commenters took the position that the EPA may not allow for tradeoffs between two pollutants in setting a NAAQS. See Section 109(b)(2) (emphasis added). These commenters suggest the NAAQS must be set for “such air pollutant” only. The EPA disagrees that the phrase “such air pollutant” in Section 109(b)(2) would prohibit the Agency from setting a multi-pollutant NAAQS in the form of an AAI. When the Administrator sets a NAAQS, the standard must be “requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of such air pollutant.” CAA Section 109(b)(2). Oxides of nitrogen and sulfur, pollutants for which the EPA has issued air quality criteria, both cause acidification of aquatic ecosystems, effects that could be considered adverse to public welfare. As such, acidifying deposition is a “known or anticipated adverse effect[] associated with the presence of [oxides of nitrogen] in the ambient air.” This known or anticipated adverse effect is also associated with the presence of oxides of sulfur in the ambient air. Given the scientific links between ambient air concentrations of oxides of nitrogen and sulfur, the related deposition of nitrogen and sulfur, and the associated ecological responses, the EPA appropriately considered a multi-pollutant NAAQS in the form of an AAI to protect against the effects of acidifying deposition to aquatic ecosystems that took into account these linkages. Rather than limiting the EPA’s authority, the language cited by the commenters goes to the breadth of the EPA’s obligation and authority to set standards to protect against “any known or anticipated adverse effects.” In addition, the NAAQS are to be based on the air quality criteria, which under Section 108(a)(2) are required to consider the kind of multi-pollutant linkage evident in this review. The EPA does not read

the language of Section 109(b) as prohibiting the Administrator from setting a multi-pollutant NAAQS such as the AAI where such an approach would be judged as the appropriate way to satisfy Section 109(b)’s requirements for each of the pollutants involved.

2. Comments on 1-Hour NO₂ and SO₂ Secondary Standards

Comments received on the proposal related to setting new 1-hour NO₂ and SO₂ secondary standards are addressed in this section. Most generally, there was broad and strong opposition to the EPA’s proposed decision to set 1-hour NO₂ and SO₂ secondary standards identical to the 1-hour NO₂ and SO₂ primary standards. For example, strong opposition to this proposed decision was expressed by a diverse set of commenters, including some environmental groups (e.g., Environmental Justice, the Adirondack Council) and industry groups (e.g., UARG, AAM, ASARCO, API, Portland Cement Association, Tri-State Generation and Transmission Association, Louisiana Chemical Association, East Kentucky Power Cooperative, FMMI, Rio Tinto), the U.S. Department of the Interior, and some states (e.g., NY, PA, TX). These commenters offered various arguments in support of their views that the proposed decision is unlawful, arbitrary, and not supported by the record of this rulemaking, as outlined below. One commenter (NC) supported setting secondary standards identical to the 1-hour NO₂ and SO₂ primary standards, while also supporting the EPA’s decision to take additional time to develop a multi-pollutant AAI-based secondary standard. Another commenter (SD) simply supported setting secondary standards that are no more stringent than the primary standards.

In proposing the 1-hour secondary standards, the EPA recognized that such standards would not be ecologically relevant, but concluded that they would nonetheless “directionally provide some degree of additional protection” by reducing deposition to sensitive ecosystems. The EPA also noted that this was consistent with the view that the current secondary standards are neither sufficiently protective nor appropriate in form, but that it is not appropriate to propose to set a new, ecologically relevant multi-pollutant secondary standard at this time.

In arguing that the proposed decision to set 1-hour NO₂ and SO₂ secondary standards identical to the 1-hour NO₂ and SO₂ primary standards is unlawful, commenters asserted that the EPA’s